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Drug Product Liability and Health Care Delivery Systems

William M. Sage*

The age of *caveat emptor* has ended. The law of product liability increasingly compensates purchasers injured by their purchases. Two trends have converged to make recovery by the plaintiff more likely today than it was in prior decades—judicial recognition of extended duties of care to distant consumers and innocent third parties, and judicial relaxation of onerous burdens of proving negligence and causation.¹ Changes in the marketplace may be responsible for the evolution of the law: distant manufacturers, complex production processes, large volume sales, national marketing, and impersonal distributors. Although traditional formulations of tort and warranty law have been adapted in a variety of ways in different jurisdictions, manufacturers are in general held strictly liable for injuries caused by defective products.²

Nowhere have changes in the law of product liability had greater effect than in the health care industry. Courts have made liability easier to prove and have upheld unprecedented damage awards.³ For example, the perceived injustice of tort law's inability to compensate injury

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1. *Barker v. Lull Engineering Co.*, 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978), exemplifies current strict product liability law.

. . . [A] product is defective in design if (1) the plaintiff proves that the product failed to perform as safely as an ordinary consumer would expect when used in an intended and reasonably foreseeable manner, or (2) the plaintiff proves that the product's design proximately caused injury and the defendant fails to prove . . . that on balance the benefits of the challenged design outweigh the risk of danger inherent in such design.

Id. at 426-27, 573 P.2d at 452, 143 Cal. Rptr. at 234 (italics omitted); see Britain, *Product Honesty is the Best Policy: A Comparison of Doctors' and Manufacturers' Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect*, 79 Nw. U.L. REV. 342, 363-67 (1984).

2. The California Supreme Court embraced the doctrine of strict liability for defective products in 1963. *Greenman v. Yuba Power Prods., Inc.*, 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963). The American Law Institute adopted strict product liability in 1964. RESTATEMENT (SECOND) OF TORTS § 402A (1964).

3. For example, the Supreme Court recently declined to review a \$4.7 million jury verdict against a spermicide manufacturer for birth defects in the child of a pregnant user. There was little scientific support for the alleged causal connection between the contraceptive jelly and the injury. *Ortho Pharmaceutical Corp. v. Wells*, 788 F.2d 741 (11th Cir.), cert. denied, 107 S. Ct. 437 (1986); see Gianelli, *Court Backs Ruling Against Spermicide*, Am. Med. News, Nov. 21, 1986, at 3, col. 1.

to unborn generations spurred judicial innovation in requirements for proof of causation in the diethylstilbestrol ("DES") cases.⁴ More recently, complications of intrauterine devices ("IUDs") led to potential manufacturer liability one thousand times greater than the profit from the product and forced the maker of one such device, the Dalkon Shield, to seek bankruptcy protection.⁵ Courts' willingness to compensate the unforeseen catastrophic losses experienced by consumers may, however, discourage product development, resulting in social harm as great as or greater than that caused by defective products.⁶

Medical products, particularly drugs and devices available exclusively by prescription, are different from other goods. Drugs must interact with the human body in order to be effective. The chemistry of the victim may contribute to an adverse drug reaction ("ADR") as much as the chemistry of the drug, as with allergic or idiosyncratic reactions; therefore, it is impossible to design an absolutely safe drug. ADRs are often indistinguishable from illnesses caused otherwise, and from symptoms of the disease the drug is meant to treat. ADRs may not become manifest for years or generations. Most importantly, extensive use in humans is the only way to measure safety or efficacy. Furthermore, consumers typically are unable to appreciate drug risks and must depend on the guidance of physicians for product selection. Many consumers are under physical and emotional burdens that may preclude true freedom of choice.

These differences between drugs and other products have led to a

4. See *Sindell v. Abbott Laboratories*, 26 Cal. 3d 588, 607 P.2d 924, 163 Cal. Rptr. 132, cert. denied, 449 U.S. 912 (1980). The *Sindell* court held that, since the plaintiff could not prove which of the DES manufacturers before the court had supplied the drug used by her mother, all defendants could be held liable according to their market share. The defendants before the court in *Sindell* were responsible for a "substantial share" of the relevant market. *Id.* at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145. See Downey & Gulley, *Theories of Recovery for DES Damages: Is Tort Liability the Answer?*, 4 LEGAL MED. 167, 168-72 (1983). Of the estimated 500,000 to 6,000,000 women exposed to DES, over 1000 have filed suit against 150 to 300 potential defendants. *Id.* at 168-72. See generally R. MEYERS, D.E.S.: THE BITTER PILL (1983).

5. A.H. Robins filed under Chapter 11 of the Bankruptcy Act after having paid \$368 million to settle 8,725 claims as of 1986. See *In re A.H. Robins Company, Inc.*, No. 85-01307-R, slip op. (E.D. Va. Aug. 5, 1987). The estimated potential liability is over \$1 billion on the sale of approximately four million Dalkon Shield IUDs, which earned Robins a net profit of about \$1 million. Thornton, *Intrauterine Devices: Malpractice and Product Liability*, 14 L. MED. & HEALTH CARE 4, 7 (1986).

6. G.D. Searle & Co. ceased production of the Copper-7 in early 1986, and there are virtually no intrauterine devices presently on the market. See O'Brien, *Increasing Liability Risks Force Health Care Products Off Market*, Am. Med. News, Jan. 2, 1987, at 30, col. 1. Although indiscriminate use and bad product design have been responsible for complications such as pelvic inflammatory disease and infertility, many gynecologists still consider the IUD the contraceptive of choice in some cases. *Id.*

A "liability insurance crisis" has forced many companies to stop producing vaccines. One of two remaining manufacturers of diphtheria-tetanus-pertussis (DTP) vaccine, Lederle Laboratories, faces lawsuits amounting to 200 times the annual gross sales of the product, even though complications arise in only one of every 310,000 recipients. Kincke, *Oral Contraceptives: Heading Into an Era of Unpredictability, Unlimited Liability, and Unavailability?*, 19 IND. L. REV. 615, 635-37 (1986) (student author).

complicated mass of exceptions to pure strict product liability. Some legal innovations may favor plaintiffs, as does market-share liability;⁷ others help defendants, as do comments j and k to section 402A of the *Restatement (Second) of Torts*, defining adequate warnings and unavoidably unsafe products.⁸

While acknowledging the above differences between medical products and other goods, the purpose of this note is to identify other, less frequently articulated assumptions about the health care industry that have influenced the development of the law in this area. Existing law reflects the health care delivery system that flourished in the 1960s and 1970s rather than the system developing today. Thus, health care in the future may be poorly served by the continuation of certain current legal trends.

This note will use the principles of law and economics to examine the interaction of market structures and product liability rules in a world of imperfect information. The goals of the analysis are to create incentives for optimal care by producers and consumers, induce the socially appropriate amount of consumption of each product (often referred to as the "activity level"), and minimize the costs of bearing the risk of injury.⁹ The note will conclude that the existence of health maintenance organizations ("HMOs") and similar prepaid providers with superior information capacity and total patient care responsibility may create a context in which current standards of drug liability should be revised.

In Part I, this note briefly describes American health care, emphasizing recent structural changes such as the emergence of large HMOs. In Part II, the note examines the interaction of the medical market structure and product liability rules. It explores two essential differences between drugs and other products: (1) the monetary costs of remedying injuries caused by prescription drugs are borne by the same market that initially purchases the product (that is, the providers and recipients of health care); and (2) nonmonetary costs (such as pain and suffering)

7. See, e.g., *Sindell*, 26 Cal. 3d at 612, 607 P.2d at 937, 163 Cal. Rptr. at 145; see also Sheiner, *DES and a Proposed Theory of Enterprise Liability*, 46 *FORDHAM L. REV.* 963 (1978) (student author).

8. Where . . . the product contains an ingredient to which a substantial number of the population are allergic . . . the seller is required to give warning . . . and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.

RESTATEMENT (SECOND) OF TORTS § 402A comment j (1964).

Unavoidably unsafe products [are] products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.

Id., comment k (emphasis in original). For prescription drugs, strict liability under the *Restatement* seems to lead to similar outcomes as would a negligence standard. See Britain, *supra* note 1, at 378-83.

9. See generally A.M. POLINSKY, *AN INTRODUCTION TO LAW AND ECONOMICS* (1983).

result not only from the use of efficacious drugs with safety hazards, but also from delay in or denial of permission to market those same drugs. The note discusses the interaction between these differences and current product liability rules in the context of emerging forms of health care, especially large HMOs with staffs of salaried physicians.

This note contends that, assuming universal enrollment in large HMOs, the imposition of liability on manufacturers for monetary damages (particularly the cost of treating drug injuries) is not particularly advantageous and creates transaction costs such as legal fees. Further, it concludes that a single standard of negligence should be applied to pain and suffering claims, regardless of whether the defendant is a drug manufacturer or a health care provider such as a hospital or a physician.

Finally, in Part III, the note discusses the inadequacy of information regarding drug risks resulting from current regulation of the development, marketing, and use of prescription drugs. It concludes that the quality of such information can be improved by (1) medical structures such as HMOs, which can gather information about delayed or low probability adverse drug reactions, and (2) intelligently selected legal rules governing physician competence and manufacturers' profit incentives.

I. THE HEALTH CARE INDUSTRY

A. *Health Care Today: Quality and Cost*

Health care is big business in the United States. In 1985, \$425 billion, or 10.7 percent of gross national product, was spent on medical care, and the figure is expected to rise.¹⁰ The recent and dramatic changes in American health care delivery may reflect a conflict between our increased ability to treat disease, matched by rising expectations of cure, and the high cost of treatment.

A confluence of forces, the most distinctive of which is consumer expectation, determines the size of the medical industry. Whether consumer expectation is the chicken or the egg in modern American health care, nowhere else in the world do people feel so entitled to purchase

10. Waldo, Levit & Lazenby, *National Health Expenditures, 1985*, 8 HEALTH CARE FINANCING REV. 1, 1 (1986). National health expenditure was 4% of GNP in 1935, 4.4% in 1950, 5.3% in 1960, 7.5% in 1970, and 9.4% in 1980. DEPARTMENT OF HEALTH & HUMAN SERVICES PUB. NO. (PHS) 82-1232, HEALTH: UNITED STATES 1981, at 195 (1981) [hereinafter HEALTH: UNITED STATES 1981]. The 50-year change in health expenditure may be in part the result of increased wealth. An Organization for Economic Cooperation and Development study has shown that rising per capita national income is associated with increased proportions being spent on health care. Waldo, Levit & Lazenby, *supra*, at 4. Certainly the large investment in health care has yielded results. A recent study showed that for every 10% increase in per capita health expenditure during the 1970s, age-adjusted mortality dropped by 1.6%. Blendon, *The Problems of Cost, Access, and Distribution of Medical Care*, DAEDALUS, Spring 1986, at 119, 131.

health and longevity.¹¹ For example, judicial decisions have required manufacturers to warn of known hazards of drug administration even when the risks are so low as to be negligible in economic decisionmaking.¹² In addition, juries may equate bad outcomes with malpractice.¹³

The counterpoint to high consumer expectations is cost containment.¹⁴ The cost of health care, whether the result of industrial avarice, rampant technology, wasteful inefficiency, or, perhaps most accurately, high expectations themselves, has become increasingly worrisome to private and public insurers.¹⁵ For example, health care expenditures when Medicare was passed in 1965 were projected to comprise only a small fraction of the total social security budget; they now make up about one third.¹⁶ Tax credits for private employee health plans, considered a minor inducement when enacted, have become critical to corporate financial planning.¹⁷ Government funding of health care is no longer unlimited. Money spent on health care either jeopardizes other programs or threatens inflation. In addition, the increasing proportion of elderly in our society will require correspondingly more medical care, a factor that adds to the concerns of budgetary planners.¹⁸

11. Expectations are much higher here than in England. See, e.g., Shine, *A Yank in London—Observations on British Medicine and Science*, 145 W. J. MED. 405 (1986).

12. E.g., *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 124 (9th Cir. 1968) (liability for failure to warn of less than 0.9 per million risk from polio vaccine).

13. See generally Reynolds, Rizzo & Gonzalez, *The Cost of Medical Professional Liability*, 257 J. A.M.A. 2776 (1987).

14. Cost containment is the most frequently discussed issue in health care today. See, e.g., Enright & Jonas, *Hospitals*, in *HEALTH CARE DELIVERY IN THE UNITED STATES* 169, 199-205 (S. Jonas ed. 1981). For a contrasting view of current high health care costs, see Conrad, *The Pharmaceutical Industry in the Year 2000*, in *PHARMACEUTICALS IN THE YEAR 2000: THE CHANGING CONTEXT FOR DRUG R & D*, 107, 111-12 (C. Bezold ed. 1983) [hereinafter *PHARMACEUTICALS IN THE YEAR 2000*] (discussing the work of Lewis Thomas and suggesting that the rise in health costs reflects a temporary bulge as society moves from "nontechnology" to "halfway technology" and that costs will again decline as "high technology" is achieved).

15. See notes 61-62 *infra* and accompanying text.

16. HEALTH INSURANCE ASSOCIATION OF AMERICA, 1981-1982 SOURCE BOOK OF HEALTH INSURANCE DATA 35 (1982) [hereinafter *SOURCE BOOK*]. The federal government's contribution to health care rose from \$7.4 billion in 1966 to \$70.9 billion in 1980. *Id.*

17. Employee health plans emerged during World War II when fixed wages made fringe benefits important bargaining tools. Tax deductions and exclusions for both employers and employees have helped maintain their popularity. V.R. FUCHS, *WHO SHALL LIVE?* 130-31 (1974). The projected 1978 "tax expenditure" for health care was roughly \$10 billion. Enthoven, *Consumer-Choice Health Plan (pt. 1)*, 298 NEW ENG. J. MED. 650, 652 (1978).

When Lee Iacocca assumed control of Chrysler, he was surprised to learn that the automobile industry's largest supplier was neither a steel nor a rubber company, but Blue Cross/Blue Shield. The cost to Chrysler of employee health benefits amounted to about \$600 for each car produced. L. IACOCCA, *IACOCCA: AN AUTOBIOGRAPHY* 306 (1984); see also Taylor, *Employment-Related Health Insurance*, in *HEALTH: UNITED STATES 1981*, *supra* note 10, at 87 (examining statistical link between health insurance benefits and three factors: size of firm, wage scale, and unionization).

18. The Social Security Administration projects that in the year 2000 there will be 36 million elderly, or 14% of the population. Goldschmidt, *Health Conditions in the Year 2000*, in *PHARMACEUTICALS IN THE YEAR 2000*, *supra* note 14, at 25, 36. By 2040, there will be 67 mil-

B. *The Historical Perspective*

At the turn of the century, neither high consumer expectations nor the need for cost containment existed. Efforts to prevent or treat disease were only variably successful, but were easily cost-justified. Independent physicians contracted with individual patients to provide a restricted range of services, which were paid for by the patients themselves.¹⁹ Most diseases were treated at home, and people typically died there.²⁰ Hospitals provided care mainly for the poor.²¹ If a drug alternative existed to the surgeon's blade or simple supportive care, the physician often compounded and dispensed it himself, although the ingredients were purchased from corporate suppliers. Adverse effects of these drugs, no doubt frequent, were less important than the simple fact that few of the drugs worked.²²

Government regulation of drugs came slowly. The Pure Food and Drugs Act of 1906,²³ the first federal legislation, was a reaction to the questionable safety of many products and the inflated advertising claims of patent medicine companies, ancestors of today's large drug manufacturers.²⁴ Such nostrums had been sold directly and through physicians for years; it was the invention of mass marketing techniques that created a problem of national importance.²⁵ The 1906 Act forced manufacturers to guarantee the accuracy of drug ingredient disclo-

lion elderly, about one quarter of the population. Gavron, *House Calls: Competition, Older Patients Prompt MDs to Hit the Road*, *Am. Med. News*, Apr. 17, 1987, at 9, col. 2.

19. See, e.g., P. STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 198-232, 352-63 (1982). Starr's book is the definitive history of health care in the United States, and underlies much of the following discussion. In contrast to the private practitioner model developing in the United States, state-hired physicians were common in Germany as early as 1818, in Russia by 1861, and in much of Europe thereafter. Greifinger & Sidel, *American Medicine: Charity Begins at Home*, in *THE NATION'S HEALTH* 124, 128 (P. Lee, N. Brown & I. Red eds. 1981) [hereinafter *THE NATION'S HEALTH*].

20. The shift toward dying in hospitals or institutions occurred during the 1930s and 1940s. In 1937, 37% of all deaths took place in hospitals or institutions; by 1980, the figure had risen to 63%. In 1980, moreover, 50% of deaths occurred in short-stay hospitals. Scitovsky, "The High Cost of Dying": What Do the Data Show?, 62 *MILBANK MEMORIAL FUND Q.* 591, 599-601 (1984).

21. By 1900, the hospital had already undergone something of a transformation from a charitable or religious institution for the general care of those who could not take care of themselves, to a bastion of science and curative medicine. See P. STARR, *supra* note 19, at 145-79.

22. Silverman and Lee call these early drugs "pink pills for pale people," which were safer but far less effective than the powerful yet toxic formulas common today. M. SILVERMAN & P. LEE, *PILLS, PROFITS AND POLITICS* 6 (1974).

23. Ch. 3915, 34 Stat. 768 (1906) (codified as amended in scattered sections of 21 U.S.C. (1982)).

24. See J.H. YOUNG, *THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION* 205-44 (1972); Newbert, *Drugs During Pregnancy: Dangerous Business—The Continued Movement to Provide Adequate Warnings for the Consumer*, 62 *NEB. L. REV.* 526, 540-45 (1983) (student author).

25. See J.H. YOUNG, *supra* note 24, at 111-24. One pharmaceutical entrepreneur offered to pay for the pedestal of the Statue of Liberty in exchange for the privilege of using it for his advertisements. *Id.* at 123.

tures.²⁶ Because of the limited number of compounds in use, full disclosure of a drug's composition was considered adequate proof of its safety, and no manufacturer testing was required.

By 1938, the sufficiency of this process was questionable. A booming chemical industry infused the original patent medicine companies, which had relied primarily on combining old ingredients in new ways, with a variety of new substances. Even physicians, increasingly under pressure from patients and drug advertisers to have the "latest," lacked the sophistication to evaluate new drugs intelligently. One result was the sulfanilamide tragedy which induced the passage of the Federal Food, Drug, and Cosmetic Act.²⁷ The Act made certain drugs available only by prescription, thereby moving the drug market away from direct advertising and sale and back to the control of the physician.²⁸ The Act also required drug manufacturers to establish the safety of new drugs before bringing them to market,²⁹ and empowered the Food and Drug Administration (FDA)³⁰ to approve and police these products.³¹

The growth of the drug industry after 1938 was staggering.³² Physicians' ability to make accurate assessments of drug risks decreased still further, especially in the face of increasingly aggressive promotional efforts by drug producers. Even FDA was dependent entirely on information provided by manufacturers. Moreover, FDA did not have the facilities to provide guidance directly to physicians, but relied on the companies to relay its recommendations honestly. FDA was not intended to perform cost-benefit analyses of new drugs, but only to assure reasonable safety. It was not until the passage of the 1962 Amendments to the Food, Drug, and Cosmetic Act,³³ spurred by the tragic injuries produced by thalidomide in Europe,³⁴ that FDA required

26. See 21 U.S.C. §§ 331, 351-352 (1982) (adulterated and misbranded drugs and devices).

27. Ch. 675, § 1, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 (1982)). Prior to the 1938 Act, drug companies verified the palatability of their new products, but not necessarily the products' safety. The legislation resulted from the disastrous attempt of one drug company to make a liquid form of the antibiotic sulfanilamide. The solvent used, diethylene glycol, caused 107 deaths, plus that of the company's chief chemist who took his own preparation in remorse. Under existing law, the Food and Drug Administration was only able to halt distribution because the drug had been "misabeled" as an elixir since it did not contain alcohol. M. SILVERMAN & P. LEE, *supra* note 22, at 86-88; Newbert, *supra* note 24, at 544-48.

28. See 21 U.S.C. §§ 331, 353(b) (1982).

29. See 21 U.S.C. § 355 (1982).

30. See 21 U.S.C. § 371 (1982).

31. For a good general history of FDA, see McClellan, Tate & Eaton, *Strict Liability for Prescription Drug Injuries: The Improper Marketing Theory*, 26 St. Louis U.L.J. 1, 9-21 (1981).

32. Lee and Silverman state that of the 200 prescription drugs dispensed most often in 1969, five were introduced before 1900, five between 1900 and 1929, nine in the 1930s, 18 in the 1940s, 95 in the 1950s, and 66 in the 1960s. By 1974, 6780 single drug entities and 3330 combination products in 14,250 different dosages and strengths were available to the average American physician. M. SILVERMAN & P. LEE, *supra* note 22, at 5.

33. Pub. L. No. 87-781, 76 Stat. 781 (1962) (codified in scattered sections of 21 U.S.C. (1982)).

34. Thalidomide achieved widespread use in Europe as a sedative during the 1950s.

manufacturers to prove drug efficacy, thereby allowing physicians to assess risk versus benefit.³⁵

If the period from 1938 to 1962 was the golden age of drugs, the period from 1955 to 1975 was the golden age of health care, when medicine truly became an industry.³⁶ Most important to this transition was the surge of optimism among consumers as to the conquerability of disease and death, and the commitment of money to that end through health insurance.

The passage of the Medicare Act in 1965 was a watershed in American health care.³⁷ Under the Act and its successors, government,³⁸ followed by private insurers,³⁹ reimbursed physicians in the traditional fee-for-service manner. Any "reasonable" care would be paid at the

Though never tested for use in pregnancy, the drug was marketed for that purpose. The tragic result was over 10,000 cases of severe limb deformities in children of users, most in Germany and Western Europe. The drug was never approved for use in the United States. M. SILVERMAN & P. LEE, *supra* note 22, at 94-98. For an account of the English experience with thalidomide, see H. TEFF & C. MUNRO, *THALIDOMIDE: THE LEGAL AFTERMATH* (1976). The settlement of all claims relating to thalidomide use in England was not achieved until 1973. *Id.* at xi.

35. Of the 4000 or so products introduced between 1938 and 1962 that were evaluated retrospectively, about half were cleared as effective, about one-quarter were classed as probably or possibly effective, and 760 were considered ineffective. About 600 had been banned from the market by 1973 for ineffectiveness. M. SILVERMAN & P. LEE, *supra* note 22, at 131. FDA's power to withdraw ineffective drugs was upheld by the Supreme Court. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973).

36. The second World War did much to increase people's expectations of medicine. Fifteen million soldiers and their families witnessed the successes of subsidized scientific care. Of those wounded who received medical treatment, less than 4% died. The American public determined not to return to the uninsured, unavailable care of the Depression years. Blendon, *supra* note 10, at 121. The war also led to widespread acceptance of federally funded and coordinated scientific research. P. STARR, *supra* note 19, at 338-47.

37. Health Insurance for the Aged Act, Pub. L. No. 89-97, tit. I, 79 Stat. 290 (1965) (codified as amended in scattered sections of 42 U.S.C. (1982)); see P. STARR, *supra* note 19, at 367-74. Medicare was passed despite, rather than because of, the medical establishment. A major behind-the-scenes force was the lobbying effort of state and local governments who wanted to shift escalating publicly financed medical care costs from the local property tax base to a social security insurance base. Ward, *Health Lobbies: Vested Interests and Pressure Politics*, in *THE NATION'S HEALTH*, *supra* note 19, at 427, 432. It is likely that fragmented medical lobbies will be unable to prevent future changes in health care delivery if there is sufficient outside support for those changes.

38. Federal, state, and local government contributions covered only 9% of the total cost of health care in 1929. Additional benefits, for example through the Veterans' Administration, increased the government's share to 21.6% in 1965, but it was the introduction of Medicare and Medicaid that was responsible for the tremendous rise in government support since that time. HEALTH: UNITED STATES 1981, *supra* note 10, at 202. In 1985, government paid 41.1% of health care costs (29.3% federal and 11.9% state and local). Waldo, Levit & Lazenby, *supra* note 10, at 13.

39. The first citywide Blue Cross Plan was attempted in 1932 and the first Blue Shield Plan in 1939. SOURCE BOOK, *supra* note 16, at 87. The percentage of personal health care funded by private insurance rose rapidly to 16.1% in 1955 and 24.5% in 1965 and has remained at about that level. HEALTH: UNITED STATES 1981, *supra* note 10, at 202. In 1980, more than 186 million Americans, 86% of the civilian noninstitutional population, had some form of private health insurance, with benefits approaching \$70 billion. SOURCE BOOK, *supra* note 16, at 6; see also P. STARR, *supra* note 19, at 235-334 (history of private insurance).

“usual and customary” fee.⁴⁰ The message to physicians was clear: The country had declared war on disease, would spare no expense, and had put doctors in command. Not surprisingly, “usual” fees increased at a much greater rate during the Medicare baseline years than they had in previous years.⁴¹

At the same time, the hospital became the health care industry's center of both technology and expense.⁴² Contrary to popular belief, hospitals do not sell services directly to patients, but rather to the physicians who admit and care for patients. Providing the latest drugs, equipment, and facilities was necessary to attract physicians. Drug companies recognized the potential for huge profits during this period, and responded with additional new products.

It is not yet clear what turned the tide against unlimited spending on health. Cost containment efforts began in the mid-1970s. Government and other large health insurers considered two general models of health care reform: socialized medicine (as adopted in the United Kingdom, Sweden and elsewhere, and espoused in the United States by Senator Kennedy) and enforced competition under a private regime. The Reagan Administration chose the latter.⁴³ Under this approach, Medicare, state programs such as Medicaid and Medi-Cal, and private insurers no longer reimburse doctors and hospitals for care actually provided. Using Diagnosis-Related Groups (DRGs), insurers pay preset amounts for the total hospital stay of patients admitted with particular diagnoses or for specified surgical procedures, no matter what amount of treatment is actually administered.⁴⁴ If hospitals and doctors provide care for less than the preset amount, they keep the excess; if the care provided costs more than the DRG reimbursement, they must absorb the loss. Whether or not it affects the quality of care, this policy is likely to squeeze out unnecessary services and high profits. Hospitals and physicians may be forced to consolidate their interests in order to negotiate more effectively with payers, such as insurance com-

40. See 42 U.S.C. § 1395(f) (1982).

41. In 1965, 1966, and 1967, physician fees rose 3.6%, 5.8%, and 7.1% respectively. The general Consumer Price Index rose 1.7%, 2.9%, and 2.9% for those three years. At no time since has the increase of fees relative to other prices been nearly so great. SOURCE BOOK, *supra* note 16, at 61.

42. See P. STARR, *supra* note 19, at 145-79; Enright & Jonas, *supra* note 14, at 169-217. The number of nonfederal short-term hospital beds increased by 68% to 848,000 between 1950 and 1970. Campbell, *The Emerging Health Care Environment: Selected Issues*, in THE PHARMACEUTICAL INDUSTRY 119, 121 (C. Lindsay ed. 1978).

43. A formulation of procompetitive regulation which influenced the Reagan Administration was Enthoven's Consumer-Choice Health Plan. Enthoven, *Consumer-Choice Health Plan* (pt. 2), 298 NEW ENG. J. MED. 709 (1978). However, the pendulum may well swing away from the market facilitation approach currently in vogue. Only about ten years ago, most observers considered the adoption of national health insurance a virtual certainty. See, e.g., M. SILVERMAN & P. LEE, *supra* note 22, at 53.

44. 42 U.S.C.A. § 1395(wv) (Supp. 1987). See generally Stern & Epstein, *Institutional Responses to Prospective Payment Based on Diagnosis-Related Groups*, 312 NEW ENG. J. MED. 621 (1985).

panies, and suppliers, such as drug manufacturers.⁴⁵ Physicians who do not perform efficiently as independents will be hired by hospitals as salaried employees. Five years ago, less than ten percent of the medical profession was salaried. The figure is now over twenty percent and rising rapidly.⁴⁶

Other changes designed to reduce the cost of health care are taking place. While DRG reimbursement and similar contractual arrangements limit the amount paid for each illness, a rise in the incidence of illness still increases total payments. It seems inefficient to provide incentives for treatment, which is compensated, rather than for prevention, which is not. Accordingly, future health care will probably be financed on a prepaid capitation basis, that is, a fixed amount per person per year.

Capitation payment is the model on which health maintenance organizations operate. At the end of 1986, twenty-eight million people were enrolled in 654 HMOs.⁴⁷ In the 1990s, twenty-five to thirty percent of the population is expected to belong to such organizations.⁴⁸ HMOs can be owned by the physicians who work in them but more often simply employ salaried doctors. HMOs frequently centralize or coordinate certain services, such as cardiac surgery or neurosurgery, and certain management functions, such as purchase of drugs and equipment. The essence of HMOs is preventive care: Profits, and even solvency, depend on keeping the costs of treatment below the sum of annual payments. The level of payment is set by hard-bargaining contributors such as insurance companies, large corporate employers, and government. A far cry from the fragmented, entrepreneurial, noninstitutionalized medicine of a hundred years ago, the HMO model is likely to be the future of much of American health care. The emergence of HMOs has important implications for prescription drugs and drug injuries, as will be shown below.

45. Multihospital systems have been growing for some time. A 1980 American Hospital Association survey indicated that about 30% of community hospital beds were operated by chains. P. STARR, *supra* note 19, at 430. In 1980, nonprofit hospitals operated 57.6% of multihospital beds, for-profit chains 35.1%, and nonfederal public systems 7.3%. Starr observes that for-profit hospital chains grew faster in the 1970s than did the computer industry. *Id.*

46. A 1981 Kaiser Foundation study included 18% salaried physicians and 77% self-employed physicians. Of salaried physicians, about equal numbers were employed by hospitals and by partnerships. LOUIS HARRIS & ASSOCIATES, *MEDICAL PRACTICE IN THE 1980S: PHYSICIANS LOOK AT THEIR CHANGING PROFESSION* 22, 24 (Study No. 804015 1981).

47. *See HMO Enrollment Reaches 28 Million Members*, Am. Med. News, May 8, 1987, at 14, col. 1.

48. Waldo, Levit & Lazenby, *supra* note 10, at 4. A 1970 comparison of HMOs and fee-for-service care showed that HMOs provided equivalent services at 73% of the fee-for-service cost. Enthoven, *supra* note 17, at 717. *See also* Meyers, *Growth in Health Maintenance Organizations*, in *HEALTH: UNITED STATES 1981*, *supra* note 10, at 75-80; V.R. FUCHS, *supra* note 17, at 138-41. *But see* Goldsmith, *The U.S. Health Care System in the Year 2000*, 256 J. A.M.A. 3371, 3373 (1986) (arguing that HMOs are not efficient care deliverers and will never supplant employer-negotiated fee-for-service care).

II. A MARKET ANALYSIS OF DRUG PRODUCT LIABILITY

No assignment of liability, whether *caveat emptor*, negligence, or strict liability, is optimal in all situations. Even within a narrow range of conditions, there will often be advantages and disadvantages to any single rule. Current product liability law emphasizes strict liability, a regime that is most efficient, according to Professor A. Mitchell Polinsky, when the following five market characteristics prevail: the probability of injury is determined exclusively by the producer, the risk is underestimated by the consumer, the producer is risk neutral, the consumer is risk averse, and insurance is unavailable.⁴⁹ In this section, the note describes the economics of prescription drug injuries and assesses the case for alternative liability schemes based on past, present, and potential health industry structures.

Consider the following scenario: Consumption of a prescription drug produces a severe adverse reaction in the purchaser, who goes to the local hospital for treatment and is not discharged for several days. The purchaser is unable to work during the period required for treatment and recovery. Medical care costs and lost income are the monetary damages caused by the accident. Value also can be assigned to the victim's physical and emotional harm, which represents the nonmonetary damages. Ideally, liability rules should minimize the total damage, that is, the sum of monetary and nonmonetary damages. The discussion below treats these two types of damages separately, although such treatment is admittedly artificial, because doing so isolates important issues in the legal response to ADRs.⁵⁰

A. *Economic Damages and Prescription Drug Injuries*

In product injuries, the cost of medical care required by the injured consumer is often the dominant component of total monetary damages. Lost income remains an element of the social cost of injury, but is comparatively unimportant in setting liability rules for ADRs.⁵¹ Therefore,

49. A.M. POLINSKY, *supra* note 9, at 103-04.

50. There are additional factors which this note will not consider at length. While economic analysis of products liability rules assumes that all costs and benefits are ascertainable from the relationship between buyer and seller, the market for prescription drugs may also produce effects outside this transactional context. For example, judicial decisions concerning public programs, such as polio immunization, often take political considerations directly into account. Vaccine cases exemplify the imposition of a duty to warn as a tool of marketplace honesty rather than as a means for preventing risk. Britain, *supra* note 1, at 389-96. Because failure to be immunized increases the risk of epidemics of contagious disease, courts consider third-party benefits of drug availability and public willingness to be treated. *See, e.g.*, *Davis v. Wyeth Laboratories*, 399 F.2d 121, 129 (9th Cir. 1968) (liability for failure to warn of less than one in 1,000,000 risk). However, the law has also provided certain unusual avenues of compensation. *See* note 98 *infra* and accompanying text.

51. For example, there are fewer associated risk-bearing costs. *See* notes 60-67 *infra* and accompanying text. Unemployment and disability compensation plans exist, insured through the government, which is risk neutral. Second, the government requires employers, largely corporations, to contribute to these plans. Although contributions are assessed per capita

this analysis focuses on medical costs as the relevant measure of monetary damages.

A major difference exists between injuries caused by health care products and those caused by other products. With other products, if the purchaser is not aware that a defect may exist, and the producer is not liable for the medical costs of the injury, then the market for the product does not take into account the cost of defect-induced medical care, creating an externality.⁵² Liability rules are therefore needed to make buyers and sellers of the product into buyers and sellers of related medical care as well. Unlike other products, however, prescription drugs are selected (and, in the case of HMOs, actually purchased) by the same health care providers who treat drug-related injuries. A market structure that gives the drug selector perfect information about the costs of treating adverse drug reactions and makes the selector consider these costs in providing prescription drugs internalizes the externality and eliminates the need for liability rules.

1. *Liability rules in the traditional health care industry.*

The market structure necessary to eliminate the need for liability rules is not that of traditional fee-for-service medicine. As noted above,⁵³ until recently the medical marketplace consisted of individual patients contracting for medical services with individual physicians, who in turn prescribed drugs manufactured by large corporations. For the purposes of this analysis, assume that the costs of the initial treatment (the drug itself) and the subsequent medical care required for the ADR are paid by the patient. Then consider the effect of individual health insurance on the analysis (assume, however, that the drug manufacturer has general liability insurance throughout).

Care and activity level. A problem with applying traditional liability rules to drugs is that the true "consumer" of prescription drugs is the physician, not the patient. Although misuse and abuse of prescription drugs such as valium by the general public remain social problems, most drugs are selected and administered by physicians rather than by patients. Since the physician will not have any economic motivation to choose and administer drugs so as to avoid injury unless she is liable for the injury, some form of physician liability is needed to supplement

and therefore disregard specific risks, and product injury is a comparatively minor cause of unemployment and disability, one can argue that a part of the lost income cost of product injury is internalized by this assignment to manufacturers. Third, many consumers of medical products are elderly people who are likely to be retired and thus will not lose income through injury.

52. An efficient level of consumption is achieved whenever the consumer considers the full social cost of the purchase, not just that part charged by the producer, in pricing the good. Ideally, consumers purchase a product until the value to them of the last unit purchased is equal to the price of that unit plus any costs, such as liability for resultant injury, which may not be reflected in the price.

53. See notes 19-42 *supra* and accompanying text.

manufacturer liability. To this end, the courts impose the negligence standard used for all medical malpractice.⁵⁴ Thus, the manufacturer is required to warn the physician of irreducible hazards and provide instructions for use, and physicians must then provide nonnegligent care. Under the "learned intermediary doctrine," the manufacturer need not warn the patient directly so long as it gives the physician the necessary information.⁵⁵

This regime of liability rules has proved to be ineffective because manufacturers' warnings are inadequate in practice even though they are legally considered to be exculpatory. When injuries occur despite warnings, manufacturers are not held liable; patients are compensated only when physicians have taken insufficient care under more lenient malpractice standards.⁵⁶ It is likely that many ADRs result from poor physician (consumer) care, much of which derives from lack of knowledge about drug risks. Indeed, there is overwhelming evidence that physicians work with inadequate information, a problem that manufacturers alone cannot remedy.⁵⁷ A regime of strict manufacturer liability without better information may therefore not be efficient in the traditional medical setting, since the injury cannot be avoided solely by the actions of manufacturers.

The physician's role as "consumer" of prescription drugs produces an even greater obstacle to the efficient operation of current liability rules than insufficient care by doctors. Because the physician selects the medically indicated treatment but does not pay for it, he does not often consider the price of a drug.⁵⁸ Even if patients would otherwise

54. See Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 50-68 (1973). Britain argues that one reason that different duties are imposed on drug companies versus physicians is that manufacturers use mass advertising to promote their products while doctors provide services on a more personal level without inflated promotional claims. Britain, *supra* note 1, at 394-96. The emergence of the large medical corporation, for example the HMO where patients rarely see the same doctor twice, casts doubt on the durability of this distinction. See text accompanying note 93 *infra*.

55. See note 74 *infra* and accompanying text.

56. One unusual feature of malpractice for drug-related injury is that a physician may be found liable for not following the manufacturer's FDA-approved instructions and precautions even though she did not fall below the community standard of care. Merrill, *supra* note 54, at 62-65; Mulder v. Parke-Davis & Co., 288 Minn. 332, 181 N.W.2d 882 (1970) (involving Chloramphenicol). However, informed consent is not as strictly required for drug therapy as for invasive medical or surgical procedures. See, e.g., Boyer v. Smith, 345 Pa. Super. 66, 497 A.2d 646 (1985).

57. See notes 113-124 *infra* and accompanying text.

58. Prior to the advent of medical cost containment, it was frequently argued that quality and availability, not price, mattered when an individual's health was involved. This rationale was used to excuse the high and variable prices of prescription drugs. See Campbell & Smith, *Profitability and the Pharmaceutical Industry*, in THE PHARMACEUTICAL INDUSTRY, *supra* note 42, at 111 ("Commonly, price is unknown to the consumer at the time the decision to use the product is made."). One reason for ignoring price may have been that there were relatively few effective medical interventions, so that a drug that worked was likely to be cost-justified at almost any price.

The "price equivalent" that has developed is the clinical "cost-benefit" analysis, which essentially reflects a general impression of safety. The accuracy of this impression depends

resist purchasing particularly expensive drugs of uncertain benefit, they will usually defer to the judgment of the physician. This results in the purchase of inefficiently large quantities of potentially dangerous drugs in the traditional health market. In economic terms, demand for a drug is highly inelastic.

Strict manufacturer liability schemes are inefficient because they rely on the classic assumption that the full cost (safe development price plus cost of treating unpreventable ADRs) will be passed along to consumers. Physicians purchase drugs for patients' accounts, and pass the risks of injury to patients, but escape liability for the costs of such injury due to the vagaries of the negligence standard. The presence of an intermediate consumer, the physician, results in economically inefficient decisionmaking which current liability rules fail to correct.

The recent rise of high-technology hospitals has exacerbated many of these care and activity level problems with strict liability. Like physicians, hospitals are generally held to a negligence standard.⁵⁹ Hospitals

on physicians having good information. Information therefore is counted twice in the economic analysis of drug use: directly, to promote efficient care by the physician-consumer when using the drug; and indirectly, as a surrogate for price, to lead to an efficient amount of drug use.

Perhaps in recognition of the importance of drug information, FDA promulgated regulations directed at forcing manufacturers to provide all relevant data to physicians, and courts imposed liability schemes (including strict liability) that attempted to correct for imperfect information. See 21 U.S.C. § 352 (1982). For example, the courts had traditionally imposed liability only for risks foreseeable considering the "state-of-the-art" at the time of sale. See, e.g., *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 426 (2d Cir. 1969). See generally Henderson, *Coping with the Time Dimension in Products Liability*, 69 CALIF. L. REV. 919 (1981); Raleigh, *The "State of the Art" in Product Liability: A New Look at an Old "Defense,"* 4 OHIO N.U.L. REV. 249 (1977). An exception was certain implied warranty claims. See *Tinnerholm v. Parke-Davis & Co.*, 285 F. Supp. 432 (S.D.N.Y. 1968), *aff'd*, 411 F.2d 48 (2d Cir. 1969) (Quadri-gen vaccine); *Stromsodt v. Parke-Davis & Co.*, 257 F. Supp. 991 (D.N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969) (Quadri-gen vaccine); cf. *Barker v. Lull Eng'g Co.*, 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978) (flaw in high-lift loader was a design defect and therefore strict liability applied). Some scholars, however, advocated liability for risks foreseeable at the time of injury. Keeton, *Products Liability—Drugs and Cosmetics*, 25 VAND. L. REV. 131, 141-44 (1972).

In *Beshada v. Johns-Manville Products Corp.*, 90 N.J. 191, 447 A.2d 539 (1982), the New Jersey Supreme Court rejected the "state of the art" defense for injuries caused by asbestos. Although limited to risks that were "reasonably knowable," the *Beshada* approach was followed for an antibiotic claim in *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374 (1984). See Fern & Sichel, *Evolving Tort Liability Theories: Are They Taking the Pharmaceutical Industry Into an Era of Absolute Liability?*, 29 ST. LOUIS U.L.J. 763, 778-83 (1985). The German drug injury compensation fund, established in 1976, adopted a similar "hindsight test." Fleming, *Drug Injury Compensation Plans*, 30 AM. J. COMP. L. 297, 300 (1982). The *Beshada* approach makes economic sense only if one doubts the completeness of the original information, given problems such as overpromotion and concealment of adverse findings.

59. Courts have generally not extended strict liability to providers of services, but have occasionally held hospitals liable for "sales-service hybrids," including injuries caused by blood transfusions and hospital gowns. See *Cunningham v. MacNeal Memorial Hosp.*, 47 Ill. 2d 443, 266 N.E.2d 897 (1970); *Thomas v. St. Joseph Hosp.*, 618 S.W.2d 791 (Tex. Civ. App. 1981); *Crowley & Johannsen, Extending Strict Liability to Health Care Providers: Can Consumers Afford the Protection?*, 13 TEX. TECH L. REV. 1435, 1444-56 (1982) (student authors). Several legislatures have excluded organ donations and blood transfusions from warranty liability. E.g., CAL. HEALTH & SAFETY CODE § 1606 (West 1979); see *Burroughs & Edenhofer, Product Liability Actions in Medical Negligence: The Barrier is Breaking*, 4 J. LEGAL MED. 201, 216-18 (1983).

frequently possess less information about drug risks than do physicians. Yet the existence of hospitals intensifies the need for better drug information. Hospitals are compelled to maintain a well-stocked pharmacy of the newest "wonder drugs"; effective competition for physician patronage means always having the latest therapies, and new, expensive drugs offer correspondingly greater profits to the hospitals. Hospitals also step between physicians and patients in the prescription process by adding pharmacy charges directly to the hospital bill, and so allow doctors to remain even less aware of cost. This phenomenon is further encouraged if hospitalization costs and physician fees are insured, so that doctors need not worry about the patient's ability to pay or their own ability to collect.

Risk-bearing costs. Unfortunately, administrative and judicial attempts to improve both care and activity level may inadvertently trigger an increase in risk-bearing costs (that is, costs arising solely from the chance of catastrophic loss).⁶⁰ Strict manufacturer liability minimizes risk-bearing costs when the manufacturer is risk neutral and the other parties are risk averse. However, even large pharmaceutical companies can only spread losses (and so be relatively risk neutral) when actuarially reasonable liability insurance is available.⁶¹ Inconsistent assignment of legal liability and highly variable jury damage awards have, to some degree, jeopardized the availability of insurance.⁶² Moreover, because companies cannot accurately estimate the risk, they cannot

Some authors suggest that there is a trend toward imposition of strict liability. *Id.* at 218-29. The emergence of prepaid health plans without itemized hospital bills may make this more difficult, since one can no longer argue that payment was made for the product apart from the services and therefore constituted a "sale."

60. Individuals place additional value on the ability to avoid risk of a loss of a certain magnitude; for example, the costs of extended medical care arising from a drug injury. See A.M. POLINSKY, *supra* note 9, at 51-56. Generally, the value placed on avoiding the risk increases directly with the amount lost as compared to the wealth of the individual. Blume & Rubinfeld, *Compensation for Takings: An Economic Analysis*, 72 CALIF. L. REV. 569, 603-04 (1984). The risk-bearing cost is equal to the amount above the actuarially fair premium (total loss multiplied by the chance of the loss occurring) which the individual would be willing to pay for insurance against the loss. The size of the risk premium indicates the degree of "risk aversion" of the individual. Individuals are generally more risk averse than are wealthy corporations. Efficient risk allocation dictates that the risk should be placed on the party best able to spread the loss or best able to buy insurance, i.e., the party which is, or can make itself, least risk averse. For a discussion of risk-bearing and drug injuries, see Britain, *supra* note 1, at 408-11.

61. See generally Smith & Cuzmanes, *Insurance Protection—Product Liability*, 40 FOOD DRUG COSM. L.J. 112 (1985). One insurance problem unique to product injuries, as compared with physician negligence, is that the former affects many victims simultaneously. An insurance company may therefore be less able to diversify the risk over other products. See Shavell, *Theoretical Issues in Medical Malpractice*, in THE ECONOMICS OF MEDICAL MALPRACTICE 35, 39 (S. Rottenberg ed. 1978). At the extreme, the risk becomes systematic and uninsurable. In England, liability insurance policies for the pharmaceutical industry frequently exclude design defects. H. TEFF & C. MUNRO, *supra* note 34, at 56.

62. For a comment on the insurance "crisis," see Gregory, *Product Liability—Insurance Problems*, LEGAL ASPECTS MED. PRAC., Mar. 1978, at 39.

purchase the optimal amount of insurance and must bear any residual risk-bearing costs.

Even insured manufacturers are not completely risk neutral.⁶³ Full insurance creates a moral hazard for the insured party. If the policy does not contain direct provisions requiring adequate care, or a deductible calculated to provide care incentives, the insured party will not take enough care no matter what the liability rule. However, deductibles and coinsurance leave risk-bearing costs on the insured party for the amount of the residual liability.

ADRs create many uninsurable risks as well, including lost sales, product recalls, bankruptcy costs, effects on stock prices, securities disclosure risks, and the threat of punitive damages.⁶⁴ Furthermore, managerial risk aversion exists regardless of the availability of insurance.⁶⁵ In addition, insurance-related disputes incur high social costs in the context of mass tort litigation.⁶⁶

Nor is it clear whether "consumers" of prescription drugs are risk averse, even in the absence of health insurance. Physicians have malpractice insurance against negligence and therefore do not bear much economic risk related to ADRs. Reputational risks may be very important for physicians, however, as may be the economic and psychological costs of malpractice litigation. The risk aversion of patients is arguably irrelevant. Patients do not often select drugs, and, at least traditionally, have been very poorly informed about risk. Bearing risks that are thought to be nonexistent is costless, no matter how large the true risk is.⁶⁷

The introduction of large-scale health insurance does not greatly alter the efficiency analysis of strict liability. Insurance coverage for drug costs further separates physicians' consumption decisions from

63. A.M. POLINSKY, *supra* note 9, at 53-55.

64. See H. TEFF & C. MUNRO, *supra* note 34, at 132; Smith & Cuzmanes, *supra* note 61, at 118-19.

65. Large corporations are often assumed to be risk neutral because of their ability to spread losses. Corporate management, however, may be highly risk averse. Their jobs may be jeopardized by risky but rational actions with adverse outcomes; boards of directors may mistake bad luck for bad decisionmaking. These risk-bearing costs cannot be insured against. See Kraakman, *Corporate Liability Strategies and the Cost of Legal Controls*, 93 YALE L.J. 857, 864-67 (1984). Managerial risk aversion may be increased by criminal liability, especially since judicial decisions have held corporate officers liable under the Food, Drug and Cosmetic Act. *E.g.*, *United States v. Park*, 421 U.S. 658 (1975). As a result, corporations may behave as if they had substantial risk-bearing costs.

66. In mass toxic torts, litigation over the division of liability among insurers is becoming nearly as great an expense as is the disposition of the claims of the victims. See Wrubel, *Liability Insurance for Insidious Disease: Who Picks Up the Tab?*, 48 FORDHAM L. REV. 657 (1980) (student author). The substitution of "claims made" for "occurrences" policies has simplified things somewhat. Smith & Cuzmanes, *supra* note 61, at 113-14. A judicial solution to defining "occurrence" for slowly progressive diseases such as asbestosis was formulated in *Keene Corp. v. Insurance Co. of N. Am.*, 667 F.2d 1034 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1007 (1982). See Smith & Cuzmanes, *supra* note 61, at 119-23.

67. In Professor Keeton's phrase, "A risk cannot be spread unless it is known." Keeton, *supra* note 58, at 141.

drug prices. Moreover, extensive insurance coverage with fee-for-service reimbursement generally means that physicians are rewarded for doing more rather than doing less, including using more or more expensive drugs, without having to consider the patient's ability to pay. In a nonspecific way, insurance does reduce patients' risk-bearing costs, assuming that patients are aware of drug risks. However, health insurance is not purchased solely for ADRs, but for a wide range of potential distress. As a result, consumer decisions whether to insure and, if so, to what degree, are typically unrelated to drug risk, as contrasted with liability insurance decisions made by manufacturers.

2. *Liability rules and the emerging HMO structure.*

The emergence of large health maintenance organizations and other integrated capitation payment schemes necessitates a different legal and economic analysis. In the future, policy may mandate that the total national financial commitment to health care be funded through direct government payment of annual capitation fees to health care providers or through incentives to taxpayers encouraging the more efficient selection of provider organizations.⁶⁸ Under such regimes, a limit is placed on the amount of money that providers can allocate to the care of patients. The most important consequence of these policies is that, unlike traditional fee-for-service physicians, neither HMOs, nor the professionals they employ, can select treatments without attention to precise economic costs and benefits, including any possible ADRs.⁶⁹

If HMO enrollment were fixed and universal, the impact of liability rules on care, consumption, and risk-bearing would be altered. With regard to manufacturer care, exemption from liability could be efficient. Since large HMOs would have to absorb the loss from avoidable injuries, they would select treatments based on full-cost risk-benefit assessment. HMOs can limit available treatment to cost-effective formularies (that is, their demand for any single drug is more elastic than that of traditional physicians and hospitals); therefore, they will negotiate to purchase drugs at a price that will yield maximum revenue to the producer if it has taken all cost-justified safety measures.

Physician (consumer) care would also improve. The HMO can edu-

68. See Enthoven, *supra* note 43.

69. This conclusion rests on the assumption that the care provider who treats the ADR is the same provider who originally prescribed the drug. This assumption is reasonable, even for adverse effects on unborn children, so long as families do not shift from one health care program to another. Professor Enthoven argues that the advantages of having continuity of care and the resultant lowered transaction costs weigh against such shifts. Enthoven, *supra* note 17, at 653. These advantages are subject, of course, to the vagaries of family mobility and provider solvency. *Id.* However, if health programs are unique to employers, job changes would make provider continuity less likely. See Goldsmith, *supra* note 48, at 3373. When ADRs caused by a drug recommended by a previous provider must be treated by a subsequent provider, a strict liability recovery of economic damages by the latter against the former might mimic the conditions present when there is no change of provider.

cate, and force compliance by, the individual doctors practicing on its behalf; it can replace the pharmaceutical company as the major source of drug information.⁷⁰ There are several reasons why the quality of information might improve in such a situation. Because large HMOs enjoy stronger bargaining positions than do individual doctors, manufacturers may engage in less raw salesmanship. The HMO would be able to employ specialists to evaluate drug information, and thus be better informed about drug risks than individual physicians who give little time or attention to such activities. Most importantly, large providers which must pay for the adverse effects caused by their errors would have both the incentive and the facilities to perform good postmarketing surveillance of drugs, thereby curing a fundamental deficiency in current ADR information. Moreover, surveillance by potentially liable providers, perhaps shared through FDA reporting requirements, would not require information exchange between parties, such as drug manufacturers and physicians, who might eventually be adversaries in litigation.⁷¹

Without manufacturer liability, consumption decisions by HMOs would nonetheless incorporate the cost of treating drug-related injuries because the HMOs must bear that cost. Since the provider would presumably both know the full cost of the drug and make purchasing decisions based on it, the efficient activity level should result. Information-gathering is part of the general emphasis on preventive care that makes the HMO an efficient care provider. While there may still be an information problem if the manufacturer's knowledge of certain drug information is superior to that of the HMO, the information-gathering incentives and abilities of large HMOs would probably overcome any tendency to understate risk.

The absence of manufacturer liability would not create risk-bearing costs in an HMO that is sufficiently large to diversify all nonsystematic risk. In addition, the patient would be risk neutral because his health care is fully covered by the capitation fee. This results from the HMO's role as both the insurer of the risk and the care provider.

HMOs also emphasize prevention to a greater degree than do traditional health care providers, which requires more direct patient participation in health care.⁷² Mass media currently provide more medical

70. Such substitution is more likely to be successful when the HMO is a single large facility rather than a loosely affiliated provider network.

71. For example, doctors have a tort action against manufacturers of defective products for both the injury to the patient and for damage to reputation and earnings, even if the doctor has previously settled an action brought by the patient against her. *See, e.g.*, *Oksenholt v. Lederle Laboratories*, 294 Or. 213, 656 P.2d 293 (1982); *Mobilia, Allergic Reactions to Prescription Drugs: A Proposal for Compensation*, 48 ALB. L. REV. 343, 364-65 (1984). In many circumstances, plaintiffs are able to play one potential defendant against another. *See generally* Willig, *Physicians, Pharmacists, Pharmaceutical Manufacturers: Partners in Patient Care, Partners in Litigation?*, 37 MERCER L. REV. 755 (1986).

72. It has been persuasively argued that an informed consumer is the best check on bad medicine. Kane, *Iatrogenesis: Just What the Doctor Ordered*, in *THE NATION'S HEALTH*, *supra* note

information to the general public (and more accurate information) than was available a few years ago to physicians. The availability of direct information benefits both the patient and the HMO. Information empowers the patient to counter the bureaucratization associated with care by a large organization. At the same time, an informed consumer is more likely to be a health maximizer outside of the hospital, preventing illness and reducing the cost of services to the HMO.

Increased patient self-determination may reduce drug abuse and misuse by the ultimate consumer. Current regulatory trends, such as patient package inserts,⁷³ and judicial innovations, such as the erosion of the learned intermediary doctrine,⁷⁴ recognize the growing role of the patient in caring for herself. HMOs and similar organizations will encourage patient education about ADRs most efficiently if the HMOs are responsible for all associated costs. It will be in the provider's interest to help the patient choose optimally among all forms of therapy, including drugs.

Of course, this is not to argue that just because HMOs increasingly define the health care industry, and because the HMOs' patients are better informed about treatment decisions, courts should withhold economic damages in drug product liability cases, or that current and evolving concepts of strict liability would not work in such a climate. However, a judicially administered compensation system has high

19, at 331-32. The centrality of personal health behavior in determining health outcome reinforces the need to educate the public. See Kennedy, *Creative Tension: FDA and Medicine*, in *THE NATION'S HEALTH*, *supra* note 19, at 335-36. Silverman and Lee favor direct patient education. M. SILVERMAN & P. LEE, *supra* note 22, at 320-22. However, one must be aware of the potential for incorrect decisionmaking created by encouraging patient-physician negotiation regarding drug treatment if patients cannot evaluate information adequately in the form it is presented. See Merrill, *supra* note 54, at 93.

73. FDA required package inserts to warn users of the risks of oral contraceptives in 1971 and of IUDs in 1980. Physician groups and the Pharmaceutical Manufacturers Association ("PMA") challenged the regulations in the courts, arguing unsuccessfully that overemphasizing risks would deter compliance with therapy. *Pharmaceutical Mfrs.' Ass'n v. FDA*, 634 F.2d 106 (3d Cir. 1980). But see Kennedy, *supra* note 72, at 335-36 (noting that direct information and professional advice are not mutually exclusive); see also M. SILVERMAN & P. LEE, *supra* note 22, at 102-03, 321-22; Kincke, *supra* note 6, at 615-18.

74. The major arguments for warning only the physician are the doctor-patient relationship and logistical problems of direct communication between manufacturers and patients. See Britain, *supra* note 1, at 375-76; Kincke, *supra* note 6, at 618-21. The learned intermediary doctrine has been eroded in two major areas where physicians may not participate intimately in patient decisions: mass immunization programs and oral contraceptives. See, e.g., *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, *cert. denied*, 474 U.S. 920 (1985). *Davis* was expressly not followed in *Walker v. Merck & Co.*, 648 F. Supp. 931 (M.D. Ga. 1986), *aff'd without opin.* 831 F.2d 1069 (11th Cir. 1987).

One can argue that prescription requirements and the learned intermediary doctrine do not protect consumers, but simply perpetuate the "information gap" and the special positions of physicians and drug companies. The alienation of the consumer from the prescription decision is worsened by health and liability insurance schemes, by professional and corporate incentives, and by the dependence of physicians for information on manufacturers. Liefmann-Keil, *Consumer Protection, Incentives and Externalities in the Drug Market*, in *THE ECONOMICS OF HEALTH AND MEDICAL CARE* 117-29 (M. Perlman ed. 1974).

transaction costs.⁷⁵ The difficulty of recovery, given administrative costs, close questions of causation and fault, inconsistency of verdicts and awards, insolvency of wrongdoers, and doctrines such as assumption of the risk, increases such costs.⁷⁶ If the health care system is evolving in a manner that allows it to deal more efficiently with the monetary losses caused by medical products injuries and to provide needed care to unfortunate victims, we should not adhere blindly to rules designed for another time.

B. *Nonmonetary Damages and Prescription Drug Injuries*

Readers of the foregoing discussion, particularly those who have personally experienced litigation involving serious personal injury, may criticize the narrow focus on monetary damages. While medical care costs may outweigh lost income in the calculation of a plaintiff's award, damages given for pain and suffering and wrongful death form the largest and least predictable element of liability.⁷⁷

Health products cause nonmonetary damages, as do other products, but they also have parallel nonmonetary benefits. Consider the consequences of repealing the Delaney Amendment⁷⁸ to the Federal Food, Drug, and Cosmetic Act,⁷⁹ which prohibits the use in humans of any drug known to be carcinogenic to animals.⁸⁰ The risk would be an increase in cancer with its attendant suffering. The benefit, however, would be to relieve the suffering of others who might be treatable with that drug. Pharmaceutical companies have long argued, with varying degrees of support from the scientific community, that the extended testing periods required in the United States, when compared with

75. It has been stated anecdotally that Eli Lilly & Co. paid one million dollars in fees to a single law firm in just three months. R. MEYERS, *supra* note 4, at 225. Liability insurance also has high transaction costs. An estimated 40% of the premium dollar covers underwriting expense and profit, 20% covers loss adjustment expenses, and only 40% benefits the plaintiff and his attorney. Fleming, *supra* note 58, at 314-15. Similarly, at least 40% of English insurance premiums is absorbed by administrative cost. H. TEFF & C. MUNRO, *supra* note 34, at 133. By contrast, only 8% of the budget for New Zealand's comprehensive accident compensation scheme represents administrative cost. Fleming, *supra* note 58, at 315.

76. Fleming, *supra* note 58, at 306.

77. The national investment in health care, particularly under a capitation system, may reflect only the economic productivity and political value associated with health. This supposedly cost-effective system may not capture, in dollar terms, the relief of suffering any more than the past system of investment limited only by the capacity of medicine to treat. If this is true, to force the health care system, or even the drug companies alone, to take into account the cost but not the benefit of the goods produced will lead to socially inefficient deterrence.

The goals of compensation and deterrence are not identical. An example is the use of punitive damages. See Shavell, *supra* note 61. Although the weight of ethical and legal tradition urges the continued compensation of nonmonetary loss, this tradition may succumb to society's inability to afford the cost of compensation, which includes both overdeterrence, given nonmonetizable social benefits, and high transaction costs produced by the tort system.

78. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified in pertinent part at 21 U.S.C. § 348(c)(3)(A) (1982)).

79. See notes 27-35 *supra* and accompanying text.

80. The Delaney Clause has been criticized as preventing the introduction of many beneficial drugs. Merrill, *supra* note 54, at 105-06 & n. 385.

other advanced countries, prolong the suffering and cause the deaths of many who would otherwise have been cured.⁸¹ The point is that, unlike the case of nonmedical products, the total nonmonetary benefits to society of prescription drugs are quite similar to the nonmonetary costs, and both are very difficult to quantify in dollar terms. Without considering individual equity, therefore, there is arguably less reason to try to measure and compensate nonmonetary drug injury.⁸²

1. *Traditional medical practice and nonmonetary damages.*

Arguments for or against various liability rules are similar for monetary and nonmonetary damages in a traditional health care system; the analysis will therefore not be repeated in this section. A full assessment of risk-bearing costs, however, requires a less theoretical perspective and must include an examination of the legal system in operation.

Let us assume that the usual forms of insurance exist for all parties: health insurance for the patient, malpractice liability insurance for the doctor, and comprehensive general liability insurance for the manufacturer. Even in these circumstances, if the patient were responsible for absorbing the cost of nonmonetary harm, his health insurance would not repay him. But does this possibility create additional risk-bearing costs? Perhaps not, or he would have chosen to insure against the risk of nonmonetary loss by purchasing a "pain and suffering" policy as well. In fact, the closest to such insurance most people buy is life insurance, which is better characterized as guaranteeing lost wages, a component of monetary damages. Similarly, physicians are relatively risk neutral because of malpractice insurance, despite the reputational risk and the residual risk created by coinsurance and deductibles. The physician is therefore fairly well shielded from risk-bearing costs of drug injury.

By contrast, even the insured manufacturer is likely to bear residual risk. As noted previously, there are uninsurable risks, such as punitive damages, which are more likely to be assessed against a manufacturer

81. The Abbreviated New Drug Application process has helped to expedite drug marketing, especially for new generic products. See 21 U.S.C. § 355(j) (Supp. IV 1986); M. SILVERMAN & P. LEE, *supra* note 22, at 136. Silverman and Lee proposed a more radical step, allowing the safety level required of a drug to vary inversely with the urgency of the need for treatment. *Id.* at 252-53. The potential benefit of AZT in halting the progression of AIDS recently encouraged similar legislation. See Bosy, *FDA Issues Final Ruling on IND Application Process*, Am. Med. News, Apr. 17, 1987, at 7, col. 1; see also Newdick, *Strict Liability for Defective Drugs and the Pharmaceutical Industry*, 101 L.Q. REV. 405, 415 (1985).

82. Some Socialist legal systems do not award damages for nonmonetary loss. H. TEFF & C. MUNRO, *supra* note 34, at 48. The Japanese Drug Side-Effect Injury Relief Fund Act of 1979 excludes nonpecuniary loss. Fleming, *supra* note 58, at 304. See also Carno, *A New Cause of Action for Massive Medical Toxic Injury*, 8 J. PROD. LIAB. 65, 71 (1985) (proposed federal cause of action for mass toxic injuries limited to pecuniary damage).

One court held that the manufacturer of a defective cardiac pacemaker was not liable under negligence or strict liability for the pain and suffering of the surgery required to install a new device, provided that the company bore the monetary cost of replacement. *Dreiling v. General Elec. Co.*, 511 F.2d 768 (5th Cir. 1975).

than against a single physician in a mass tort. Moreover, a company that makes only a few patented, highly profitable drugs is poorly diversified, so that the threat of failure of a leading product essentially represents a systematic risk.

In addition, it may be difficult to obtain actuarially fair insurance. The so-called "insurance crisis" indicates the high level of risk-bearing costs placed on insurers in product liability suits. Jury awards for non-monetary damages are partly responsible, especially because of the unpredictability of the amount awarded. An even greater problem is uncertainty in determining liability, and the threat of high damages if liability is found. This problem results from various judicial innovations that courts have introduced in litigation over prescription drug injuries, such as alternative liability,⁸³ concert of action,⁸⁴ market share liability,⁸⁵ and risk-contribution liability.⁸⁶ There are even more extensive variations among jurisdictions in their requirements for adequate warnings and the foreseeability of risks, in their interpretations of express and implied warranties, in their assignments of burdens of proof of causation,⁸⁷ in their statutes of limitations,⁸⁸ in their treatment of unavoidably dangerous products,⁸⁹ and in their definitions of defect.⁹⁰

This lack of uniformity not only makes the search for compensation into something of a lottery,⁹¹ but imposes significant costs on the par-

83. *Summers v. Tice*, 33 Cal. 2d 80, 199 P.2d 1 (1948). The theory of alternative liability requires that all the possible defendants come before the court in order to assign responsibility to each. For this reason, the theory has not been used very successfully by victims of DES. *Downey & Gulley*, *supra* note 4, at 182-85. *But see* *Abel v. Eli Lilly & Co.*, 94 Mich. App. 59, 289 N.W.2d 20 (1980), *modified*, 418 Mich. 311, 393 N.W.2d 164 (1983), *cert. denied sub nom. E.R. Squibb & Sons, Inc. v. Abel*, 469 U.S. 833 (1984) (all likely defendants present); *Fern & Sichel*, *supra* note 58, at 776-78.

84. *Bichler v. Eli Lilly & Co.*, 55 N.Y.2d 571, 436 N.E.2d 182, 450 N.Y.S.2d 776 (1982); RESTATEMENT (SECOND) OF TORTS § 876 (1976); *Downey & Gulley*, *supra* note 4, at 173-78.

85. *See* note 4 *supra*.

86. The risk-contribution theory allows recovery against a maker who could have supplied the drug taken because the maker produced and marketed the drug, thereby contributing to the risk of injury. *Collins v. Eli Lilly & Co.*, 116 Wis. 2d 166, 342 N.W.2d 37, *cert. denied sub nom. E.R. Squibb & Sons, Inc. v. Collins*, 469 U.S. 826 (1984); *Fern & Sichel*, *supra* note 58, at 772-73. Recovery under the theory may be limited to market share. *Martin v. Abbott Laboratories*, 102 Wash. 2d 581, 689 P.2d 368 (1984) (en banc); *Fern & Sichel*, *supra* note 58, at 774-76.

All of these causation doctrines have been applied in the DES cases. *See* *Downey & Gulley*, *supra* note 4, at 173-90; *Fern & Sichel*, *supra* note 58, at 765-76; *Newdick*, *supra* note 81, at 420-30. In response to liberal theories of causation, drug companies have improved their recordkeeping of product distribution and market share, and have introduced distinguishing features to their brands such as unusual shapes and colors. These defensive moves are not costless. *Fern & Sichel*, *supra* note 58, at 784. *But see* *Leighton, Market Share Liability: The Need For a Uniform Market Share Liability Act*, TRIAL, Nov. 1985, at 84 (suggesting that market share liability may be a disincentive to recordkeeping).

87. *See* notes 83-86 *supra* and accompanying text.

88. *See generally* *Wanger, Medical Products Liability and the Statute of Limitations*, 32 MED. TRIAL TECH. Q. 192 (1986). Additionally, the statute of limitations varies with the medical defendant chosen by an injured plaintiff: physician, hospital, pharmacist, or manufacturer.

89. *See* note 8 *supra* and accompanying text.

90. *See* notes 1 & 8 *supra* and accompanying texts.

91. For example, the facts of the MER/29 injuries were clear, yet of five reported cases,

ties held liable. Notwithstanding uniform FDA regulations, differences in the states' standards regarding adequacy of warnings can force manufacturers to label, package, and distribute drugs in unnecessarily expensive ways. More importantly, medical products are becoming uninsurable; there is sufficient uncertainty in estimating product risk to force insurers to set excessive premiums, leaving large risk-bearing costs on uninsured manufacturers.

If commercial insurance is unavailable, and producers are unable to self-insure against risks of astronomical liability, manufacturers may make inefficient production decisions. Consider two painkillers: Compound A costs twice as much to produce as compound B. When given to people other than pregnant women, both are equally effective. When given to pregnant women, however, compound A is clearly more effective. Both compounds have the same low rate of complications in pregnant women. The economically efficient solution is for compound A to be used by pregnant women and compound B by everyone else. But given the potential liability of a drug used exclusively in pregnancy as compared with one where the risks of use in pregnancy can be spread among nonpregnant users, it is likely that compound A will not be produced, and compound B will be used by everyone.⁹²

2. HMOs and nonmonetary damages.

Inefficiencies such as those in the drug example above are made more likely by the fact that different legal rules attach to drug manufacturers than attach to other participants in the health care market. As discussed previously, assigning strict liability to drug companies and negligence liability to hospitals and physicians makes economic sense only under certain conditions: where the companies alone have perfect information, where aggressive marketing techniques exist, and where the hospital-physician-patient relationship is intimate and personal. Where prepaid health care is provided through large HMOs, strict liability is less advantageous for several reasons.

First, the doctor-patient relationship differs from the traditional model. Continuity of care with a single physician is less likely, so that physicians may be less conscious of patients' preferences in presenting

plaintiffs won only two because of different legal standards and inconsistent judicial interpretations. Merrill, *supra* note 54, at 41-43; see note 127 *infra*. Similar results occurred for Aralen injuries (six of nine verdicts for plaintiffs) and Chlormycetin complications (two of three). Merrill, *supra* note 54, at 43-49; see note 118 *infra* and accompanying text. Federal statutory standards for mass medical torts have been proposed. Carno, *supra* note 82.

92. For a somewhat similar argument regarding drugs for suppression of preterm labor, see Wilson, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 *FORDHAM L. REV.* 735, 758 (1980) (student author). The hypothetical also resembles the story of Bendectin, an anti-nausea drug that was removed from the market following reports of birth defects in children of users. See Leatham, *Safety and Efficacy of Antiemetics Used to Treat Nausea and Vomiting in Pregnancy*, 5 *CLINICAL PHARMACY* 660 (1986); *Girl Awarded \$1 Million in Bendectin Lawsuit*, *Am. Med. News*, Oct. 10, 1986, at 12, col. 3.

care decisions. Second, hospitals no longer passively respond to the demand of physicians for products, but control the practices of their employees. Existing liability rules assume, to some degree, that traditional physicians make decisions with little regard for cost. By contrast, HMOs are run by professional managers who typically make economically rational decisions.

For example, doctors' choices of treatments in HMOs may be affected more by the policies of the provider organization than by the continued invention and promotion of new products by manufacturers. If an HMO, even non-negligently, restricts its formulary to a risky drug and denies its physicians access to alternatives, it is neither efficient nor equitable to hold the drug manufacturer strictly liable for injuries caused by the product while the HMO escapes liability. Moreover, in deciding to use a certain drug, the HMO does not compare that drug only to other drugs, but also to surgical care, other medical care, and no care at all. If a drug manufacturer is held strictly liable for drug injuries regardless of HMO negligence, but the HMO is held to a negligence standard for surgical injuries, a rational HMO administrator will perceive the drug as having a lower cost than the surgical intervention, given the same risk of HMO negligence, and will therefore overconsume drug therapies.⁹³ If truly cost-efficient care decisions are to be encouraged, these illusory cost differences must be eliminated.

Finally, HMOs may be as able to insure against risks as drug manufacturers, and arguably are better able to do so. HMOs have no systematic drug risks and they spread insurance liability over a broad group of participating physicians with diversified competences.

As this analysis indicates, manufacturers of medical goods and providers of medical services are coequals in profit motivation and risk-bearing capacity in a future health care delivery system dominated by large HMOs. A persuasive argument can be made for a uniform liability standard for both manufacturers and providers. For several reasons, negligence appears to be the best standard.⁹⁴

Negligence could be applied confidently to both the health corporations and their employees, such as physicians and nurses. Moreover, under comparative negligence principles,⁹⁵ liability and hence risk-

93. Overuse of drug therapies could be avoided by imposing strict liability on the manufacturer with a defense of contributory *physician* negligence. Merrill, *supra* note 54, at 107-12. Such a system might, however, make compensation slightly more difficult for the victim.

94. Strict liability as a single standard has also been considered. Crowley & Johannsen, *supra* note 59; Burroughs & Edenhofer, *supra* note 59. For drug cases, strict liability might be imposed against other health care providers only if recovery from the manufacturer is unavailable. MODEL UNIFORM PRODUCT LIABILITY ACT, 44 Fed. Reg. 62,727 (1979); Caldwell, *Products Liability and Medical Devices: Diagnosis and Cure*, 87 DICK. L. REV. 779, 796-97 (1983) (student author).

95. Willig has suggested that a comparative fault approach be applied in cases where physicians, pharmacists, and manufacturers are named as defendants in a single drug injury case. Willig, *supra* note 71, at 786-88; cf. *General Motors Corp. v. Hopkins*, 535 S.W.2d 880

bearing costs could be spread if available information did not lead to the expected levels of care, or if judges or juries made mistakes. A uniform comparative negligence standard might lead to the eventual adoption of true probabilistic compensation (that is, an award of damages equal to the cost of injury multiplied by the chance of causation by the drug) for injuries, such as cancer, the causes of which can never be established with certainty.⁹⁶

Lawyers and judges remain comfortable with arguments based on negligence, and it would be easier to achieve uniformity among jurisdictions with a negligence standard, reducing the uncertainties on insurers. Additionally, under a universal negligence standard, courts and health care participants would be more likely to accept FDA regulations on prescription drugs as the standard of care. Whether by formal pre-emption, or state by state adoption, a federal law of product liability might result, bringing with it additional benefits of uniformity and predictability. Finally, negligent behavior would most likely indicate information failure, and payment of damages could be seen as an incentive to improve the information.

A negligence standard for medical product liability cases would allow more general approaches to tort reform to go forward unencumbered by the idiosyncrasies of existing case law involving drug injuries.⁹⁷ Such reform might include elimination of contingent fees, limitations on nonmonetary damages, or compulsory arbitration. Unlike proposals for no-fault drug compensation schemes,⁹⁸ which single

(Tex. Civ. App. 1976), *aff'd*, 548 S.W.2d 344 (Tex. 1977) (product misuse reduced product liability award according to comparative fault principles).

96. When it is uncertain that a product caused a particular injury, all-or-nothing liability will be inefficient. For example, if the product is 95% likely to have caused the injury, the tort system will generally hold the manufacturer liable. If the chance is 5%, the producer will frequently be absolved. Neither outcome is efficient, the former inducing excessive care and suboptimal purchasing, and the latter insufficient care and excessive purchasing. Cornell, Noll & Weingast, *Safety Regulation*, in *SETTING NATIONAL PRIORITIES: THE NEXT TEN YEARS* 464-77 (H. Owen & C. Schultze eds. 1976).

97. Tort reform acts, many with liability caps, were passed in 37 states in 1986. Rust, *Malpractice: New Alliances Aid in Passage of Tort Reforms*, *Am. Med. News*, Jan. 2, 1987, at 3, col. 1. State courts have divided on the constitutionality of such laws. Reidinger, *Malpractice Cap Blasted*, *A.B.A. J.*, Feb. 1, 1987, at 70, 72. For example, a federal district court recently declared unconstitutional a Virginia statute that placed a ceiling on medical malpractice recovery. The court held that the statute, by limiting the role of the jury in assessing damages, violated the seventh amendment's guarantee of jury fact-finding. *Boyd v. Bulala*, 647 F. Supp. 781, 788-90 (W.D. Va. 1986).

98. Compensation funds for special classes of injury have been criticized as political compromises that reduce horizontal equity as much as do inconsistent jury verdicts. Fleming, *supra* note 58, at 317-19. Following the thalidomide disaster, West Germany required pharmaceutical companies to contribute to a fund to compensate victims of subsequent incidents. Sweden and Japan have also enacted comprehensive drug injury compensation plans. *Id.* at 298-304; see also H. TEFF & C. MUNRO, *supra* note 34, at 138-42; Newdick, *supra* note 81, at 428.

The public goods nature of vaccines makes them attractive choices for special compensation funds. All states require children to undergo vaccination. However, vaccines carry small but significant risks of serious injury or death. Because the threat of manufacturer liability inhibits production of vaccines, and injury results directly from compliance with state regula-

out groups of plaintiffs for special treatment, return to a single rule would promote comprehensive change in the law as a whole.

The drawback of a negligence standard is that the victim remains uncompensated if other parties behave non-negligently. However, given the valuation problem and the fact that people do not choose to insure against nonmonetary injury, there are few risk-bearing costs on individuals. Therefore, the absence of compensation may be acceptable.

A uniform federal negligence standard for many products may be adopted in the near future. Early in 1986, the Reagan Administration's Tort Policy Working Group drafted, and Senator Robert Kasten introduced, a measure to preempt state product liability law under Congress's broad powers to regulate interstate commerce.⁹⁹ The Kasten bill was overtaken in committee by a bill drafted by Senator John Danforth,¹⁰⁰ which passed the Commerce Committee in June, 1986, but was never brought to a vote on the Senate floor. Both 1986 proposals were daring attempts to sweep away the clutter of inconsistent state laws affecting products manufactured and marketed nationally, such as prescription drugs, in favor of a uniform negligence standard. Congress continues to draft and debate similar measures, and solidification of lobbying interests representing the health care industry may hasten their adoption.¹⁰¹

tion, there has been a greater willingness to compensate victims at public expense than for other drugs.

In 1976, Congress provided an exclusive remedy against the government for injuries resulting from the swine flu immunization program. Swine Flu Act, Pub. L. No. 94-380, 90 Stat. 1113 (amending 42 U.S.C. § 247(b) (1976)); see *Ducharme v. Merrill-Nat'l Labs.*, 574 F.2d 1307 (5th Cir.), cert. denied, 439 U.S. 1002 (1978). England has a no-fault government compensation scheme for vaccine injuries to children causing 80% or greater disability as judged by a tribunal. *Diamond & Laurence, Product Liability in Respect of Drugs*, 290 BRIT. MED. J. 365, 366 (1985). The National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986) (codified in scattered sections of 42 U.S.C.), is the most recent compensation proposal. The Act provides a nonexclusive remedy against the government with direct recovery from the manufacturer only for negligence. Government compensation is similar to workers' compensation, prohibiting the award of punitive damages and limiting nonmonetary damages and wrongful death recoveries to \$250,000. 42 U.S.C.A. § 300aa-15 (West Supp. 1987); see Gianelli, *Veto Warned If Vaccine Law Funded by New Tax*, Am. Med. News, Mar. 20, 1987, at 2, col. 1.

99. S. 100, 99th Cong., 1st Sess., 131 CONG. REC. S217-23 (1985). The Model Uniform Product Liability Act, drafted in 1979, reflected an earlier attempt to standardize product liability law. 44 FED. REG. 62,714 (1979). Broadly summarized, the Uniform Act applied strict liability to manufacturing defects and express warranties, and negligence to design defects and failures to warn. See Wilson, *supra* note 92 at 740-46; Caldwell, *supra* note 94, at 790-97.

100. S. 999, 99th Cong., 1st Sess. (1985); see also Roberts, *Products Liability Bill Nears Approval by Senate Committee*, L.A. Daily J., June 26, 1986, at 21, col. 1.

101. Currently, 221 federal agencies and departments, and a much larger number of state regulatory bodies, share responsibility for health care. Stevens, *The Federal Government and the Health Care System*, in THE NATION'S HEALTH, *supra* note 19, at 419. Lobbying groups, other than a few industrial interests such as PMA, are organized on a craft basis, are split between manpower (such as the American Medical Association) and facilities (such as the American Hospital Association), or are narrowly focused on single diseases. Should large

III. THE INFORMATION PROBLEM AND THE DRUG INDUSTRY

Even with liability rules, the traditional medical marketplace does not provide proper care incentives in the selection and use of drugs because of information failure. Economic theory suggests that if perfect information exists, parties will take cost-justified care no matter which party is liable.¹⁰² In the drug industry, courts have assumed that the manufacturer, and only the manufacturer, has access to such information. As a result, courts have provided manufacturers with incentives to prevent foreseeable injuries, in the form of liability based on either negligence or strict liability.¹⁰³

Why, then, do "preventable" ADRs occur? First, drug manufacturers may not be using available information; second, there may be insufficient information upon which to base decisions; and third, drug consumers (physicians and/or patients) may be taking insufficient care despite the best efforts of the manufacturers. The inadequacy of postmarketing surveillance for FDA-approved drugs makes the second possibility appealing. At the time a drug is approved, many adverse effects are undiscoverable. Though the first such ADRs to arise are unpreventable, effective postmarketing surveillance can greatly reduce the total damage. Courts have begun to recognize this fact and are reshaping legal standards in order to induce manufacturers to monitor their products.¹⁰⁴ If successful, this approach might ensure adequate producer care. However, manufacturers may not be well suited to gather this information because of transaction costs and other

corporate medicine come to dominate American health care, lobbying efforts may increase greatly in unity and power. Ward, *supra* note 37, at 431, 433.

102. If there is perfect information, there are no risk-bearing costs, and the chance of injury is unrelated to the conduct of the parties (i.e., the product cannot be made safer, hence negligence is not an issue), an efficient level of activity will also be obtained whether the consumer is made to bear the loss or the manufacturer is held strictly liable.

If there is no liability, the consumer will add the actuarially fair cost of injury to the price of the product and will buy only the amount that is cost-justified. If there is strict liability, the price of the product will include the cost of injury (cost of injury becomes a cost of production which must be passed along), and the consumer will again buy the proper amount. This is an application of the Coase Theorem. See A.M. POLINSKY, *supra* note 9, at 96-97; see also Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1 (1960).

103. Inadequate consumer information is the core justification for strict liability rules. See Goldberg, *The Economics of Product Safety and Imperfect Information*, 5 BELL J. ECON. & MANAGEMENT SCI. 683 (1974). For a discussion of information and consumer autonomy, as opposed to market efficiency, see Turner, *Computers, Consumers and Pharmaceuticals*, in PHARMACEUTICALS IN THE YEAR 2000, *supra* note 14, at 129.

104. In particular, at least one court has rejected the "state of the art" defense. *Beshada v. Johns-Manville Products Corp.*, 90 N.J. 191, 447 A.2d 539 (1982). *But see* RESTATEMENT (SECOND) OF TORTS. § 402A, comments h & i (1964) (limiting strict liability to risks reasonably foreseeable at the time of sale). Principles of law and economics suggest that truly unforeseeable effects should not be charged to the manufacturer, because they cannot affect the standard of care. Moreover, risk-bearing costs will not be minimized because it is impossible to insure accurately against unforeseeable risk. See, e.g., Wilson, *supra* note 92, at 753, 757. The usefulness of the "state of the art" defense is somewhat limited by the continued redefinition of foreseeability based on technology and care actually taken, so that fear of such liability may result in an improved "ability to foresee." See also Fern & Sichel, *supra* note 58, at 778-85.

problems.¹⁰⁵

Whatever the choice of liability rule, additional structural and legal devices that improve the quality of information will promote efficient use of potentially dangerous products. The size and complexity of American medicine increase the risk of information failure in the delivery of care involving powerful drugs. Centralized regulation and liability standards promoting information development offer the best means of reducing this risk.¹⁰⁶ Current regulatory tactics often fail, however, because of inadequate monitoring and reporting of adverse drug reactions and because of overenthusiastic marketing by drug companies.

A. *Pharmaceutical Industry Practices and ADRs*

The pharmaceutical industry has grown commensurately with the rest of the health care system. In 1978, American drug firms employed 178,000 workers, and reported domestic sales of \$9.4 billion and international sales of \$6.6 billion.¹⁰⁷ Doctors in the United States wrote 751 million new prescriptions and 658 million refills, accounting for eight percent of national health expenditures.¹⁰⁸ Pharmaceutical manufacturers have earned consistently higher profits than have producers in other sectors of the economy.¹⁰⁹ Drug therapy has contributed greatly to the public welfare, however, and few would begrudge the industry monopoly returns on many patented innovations given that, under current regulatory standards, drug development is very slow and very expensive.¹¹⁰

An especially controversial aspect of the industry is drug promotion.

105. See notes 134-136 *infra* and accompanying text.

106. For a comparison of liability rules and regulatory schemes in the efficient modification of behavior, see Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357 (1984).

107. PHARMACEUTICAL MANUFACTURERS ASSOCIATION, PRESCRIPTION DRUG INDUSTRY FACT BOOK 15-16, 55 (1980) [hereinafter PMA FACT BOOK].

108. *Id.* at 15, 21.

109. M. SILVERMAN & P. LEE, *supra* note 22, at 29-30. In 1975, for example, the drug industry had a pre-tax return on equity of 27.7%, compared with 18.9% for all manufacturing industries. PMA FACT BOOK, *supra* note 107, at 53.

110. According to a 1971 estimate, 90% of drug development projects fail, while each successful project takes five to seven years and costs approximately \$12 million. These statistics compare with a 63% failure rate, development time of two years, and cost of \$0.5 million for projects completed before the 1962 amendments. Schnee & Caglarcan, *Economic Structure and Performance of the Ethical Pharmaceutical Industry*, in THE PHARMACEUTICAL INDUSTRY, *supra* note 42, at 96. The number of new drugs introduced each year declined from an average of 39 between 1956 and 1960 to 12 between 1966 and 1970. *Id.* at 93-94. More recent estimates put the cost of a new drug at about \$70 million. Bezold, *An Overview*, in PHARMACEUTICALS IN THE YEAR 2000, *supra* note 14, at 30.

However, much drug development involves inventing around existing patents and devising "me-too" drugs; that is, drugs that can be vigorously promoted as new brands by the manufacturer, even though they have no therapeutic advantages over existing products. A former director of research at Squibb estimated that 75% of funds were spent on "me-too" drugs and unimportant combination products. M. SILVERMAN & P. LEE, *supra* note 22, at 40. The abundance of "me-too" products is demonstrated by the fact that the 200,000 or so over-the-counter drugs currently sold without prescription are composed of only about 250 active

Drug companies spend nearly as much money on promotion as American medical schools spend on all their educational activities.¹¹¹ The bulk of promotional money is spent on "detail men," high-powered, variably knowledgeable sales representatives who visit physicians individually and may urge, cajole, bully, or bribe them to use a company's latest and usually most expensive products.¹¹² These tactics reflect manufacturers' desires to earn back sunken costs quickly and turn a profit before a competitor invents a superior drug.¹¹³ The problem is that drug manufacturers are the dominant if not only source of information about drug risks and benefits for most prescribing physicians. The oral communications of detail men cannot be monitored for completeness or accuracy, no matter what control FDA asserts over the required package insert warnings or the contents of journal advertisements.¹¹⁴ Moreover, because revenue from drug advertising is essential to the publication of virtually all medical journals, journals may be reluctant to publish research criticizing proprietary products.¹¹⁵

Other information sources similarly reflect the interests of drug

ingredients. *Id.* at 208. High industry profits are less socially justifiable for "me-too" drugs than for truly innovative products.

111. M. SILVERMAN & P. LEE, *supra* note 22, at 54-55. A 1975 report stated that 27% of sales is spent on marketing. Harrell, *Pharmaceutical Marketing*, in *THE PHARMACEUTICAL INDUSTRY*, *supra* note 42, at 80. Drug marketing has been compared to the gaudy, rapid-turnover environments of automobiles and fashion. S. GREENBERG, *THE QUALITY OF MERCY* 269 (1971). In England, by comparison, 14% of total drug sales in 1975 was spent on promotion, while 7 to 13% was spent on research and development. H. TEFF & C. MUNRO, *supra* note 34, at 104.

112. The industry employed 39,000 people in marketing and distribution in 1978. PMA FACT BOOK, *supra* note 107, at 56. A 1973 AMA survey indicated that over 50% of AMA members believed that sales representatives had a "marked" or "moderate" influence on their prescribing habits, less than the effect of the *Physician's Desk Reference* (84%), *see* note 116 *infra*, but double that of the printed forms of advertising that FDA can monitor easily. Harrell, *supra* note 111, at 73.

113. Because companies must recover their investments quickly, the incentives for a company, once a drug has been released, are to suppress adverse information, conduct blitzkrieg advertising campaigns, and delay FDA regulatory actions. In 1969, for example, Upjohn challenged an FDA order removing the combination antibiotic Panalba from the market. Upjohn asserted that FDA was required to conduct an evidentiary hearing entering the order. *Upjohn Co. v. Finch*, 422 F.2d 944 (6th Cir. 1970). Upjohn earned \$1.5 million per month from Panalba sales until the court affirmed FDA's order several months later. S. GREENBERG, *supra* note 111, at 273-74.

114. The drug companies vigorously opposed FDA efforts to regulate drug advertising under the 1938 Act. FDA ultimately prevailed. *United States v. Urbuteit*, 335 U.S. 355 (1949). To police and remedy false or misleading claims, FDA uses "Dear Doctor" letters. Under the threat of seizure of the "misbranded" goods, FDA forces drug companies to notify all practicing physicians of misstatements and corrections. M. SILVERMAN & P. LEE, *supra* note 22, at 64-65. One difficulty with regulating advertising is that there must be advance approval of all promotional material, which is expensive and time-consuming, in order to stop a fraudulent campaign before it has influenced physicians. This regulatory problem is especially acute for over-the-counter drugs, for which the general public is the target of advertising. *Id.* at 222. In Sweden, all drug advertising is banned from television. *Id.* at 220. Detail men, one should remember, are essentially unregulable.

115. For example, in 1974, the *Journal of the American Medical Association* received over \$7 million in advertising revenues, or more than \$50 per subscription, from drug manufacturers. M. SILVERMAN & P. LEE, *supra* note 22, at 52; *see also* S. GREENBERG, *supra* note 113, at 267-83.

manufacturers. The bible of drug therapy, the *Physicians' Desk Reference* ("PDR"), is supported wholly by manufacturers.¹¹⁶ The few truly neutral sources of information are buried in a mass of promotional material.¹¹⁷ Overpromotion by drug companies has been implicated in many drug injuries, most notably in the continued overuse and misuse of the antibiotic chloramphenicol (Chlormycetin) despite fatal bone marrow suppression in a small percentage of users.¹¹⁸ Courts have on occasion recognized that promotional efforts by drug manufacturers may negate the protection afforded by FDA-required warnings.¹¹⁹

The combination of an abundance of powerful medicines and a scarcity of reliable information as to their costs, risks, and benefits has created a drug problem of frightening proportions. Abuse and misuse by the public contribute to the danger, but the great majority of injuries results from the legitimate use of drugs prescribed by physicians.

Prescribing drugs, particularly given patients' high expectations, has taken on ritual significance.¹²⁰ Unfortunately, many physicians are uninformed about the dangers associated with the drugs they prescribe.¹²¹ About one third of hospitalized patients experience adverse

116. The PDR was the source most likely to "markedly" influence the prescribing habits of 96,950 doctors replying to an AMA survey in 1973. The PDR is widely accepted as a scientific publication. In reality, however, it is nothing more than a compilation of package inserts purchased as paid advertising by drug companies. M. SILVERMAN & P. LEE, *supra* note 22, at 75.

117. A few publications, such as AMA DRUG EVALUATIONS and *The Medical Letter*, do provide unbiased drug information. *Id.* at 79-80, 307; Kennedy, *supra* note 72, at 334-35; Turner, *supra* note 103, at 132. Unfortunately, *The Medical Letter* has few subscribers, probably only one in ten prescribing physicians. S. GREENBERG, *supra* note 111, at 288.

118. Despite conclusive evidence of the drug's danger and the fact that it was superior to other antibiotics in only a handful of emergencies, Parke-Davis downplayed the drug's toxicity so effectively that ten years after the discovery of its adverse effects, Chlormycetin was being prescribed wrongly in about 90% of cases, including for acne and the common cold. M. SILVERMAN & P. LEE, *supra* note 22, at 59-61, 283-88.

119. *See, e.g.*, *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967).

120. Prescribing may be a social act: "a means of terminating the interview in a fashion that satisfies both doctor and patient." M. SILVERMAN & P. LEE, *supra* note 22, at 304. If true, this interpretation helps explain the widespread use of DES for infertility. R. MEYERS, *supra* note 4, at 92. In England, over 70% of consultations with family doctors result in a prescription. H. TEFF & C. MUNRO, *supra* note 34, at 110. Silverman & Lee attribute the current public belief that "there *must* be . . . a chemical answer to every physical, emotional, and sociological discomfort of mankind" to the heavy advertising of over-the-counter drugs. M. SILVERMAN & P. LEE, *supra* note 22, at 22; *see also* S. GREENBERG, *supra* note 111, at 288-92. The figures are more worrisome considering that about 60% of patients who visit a general practitioner do so largely for nonmedical reasons, such as loneliness. M. SILVERMAN & P. LEE, *supra* note 22, at 293-94. It has been estimated that "at least \$6 of every \$10 spent on drugs outside of the hospital is unnecessary." *Id.* at 291 (quoting the chairman of the New York State Public Health Council). Overuse of medicines is a problem worldwide. Data compiled by the Organization for Economic Cooperation and Development (OECD) indicate that in 1977 the average American used 4.3 medicines. The lowest yearly use in the 16 countries reporting was 1.3 in Japan; the highest was in France, an astonishing 24.1. OECD, OECD SOCIAL POLICY STUDIES No. 2, MEASURING HEALTH CARE 1960-1983 87 (1985).

121. For example, a study of antibiotic prescribing revealed that only 12.9% of uses were evaluated as rational, 21.5% were considered to be questionable, and an amazing 65.6% were judged irrational. M. SILVERMAN & P. LEE, *supra* note 22, at 289-90. Even accomplished

drug reactions, and ADRs account for about three percent of all general medical hospital admissions.¹²² The cost to society of caring for these complications is roughly equivalent to the cost of all drugs used.¹²³ This is especially troublesome because seventy to eighty percent of ADRs are likely to be preventable.¹²⁴

B. Current Regulation

The difficulty of identifying and communicating the hazards of prescription drugs may explain both FDA's regulatory mission and the imperfect success the agency has achieved. FDA, perhaps recognizing the impossibility of ensuring complete and effective disclosure of risks by manufacturers,¹²⁵ instead verifies the safety and efficacy of new drugs before approving them for general distribution.¹²⁶ The agency requires a lengthy three-phase experimental protocol before a drug may be marketed. Thereafter, the manufacturer must periodically review the drug's safety and efficacy in the population at large.

There are several major problems with the FDA approach, the most obvious of which is the agency's complete dependence on manufacturers for information. Manufacturers perform all premarketing tests and collect all postmarketing results. Drug regulation's short history is replete with episodes of falsification and concealment of research by manufacturers, the best known being the triparanol (MER/29) experience.¹²⁷ Since a manufacturer may have invested several million

academic physicians are unable to evaluate the flood of new drugs without relying on the promotional literature distributed by manufacturers and their detail men. *Id.* at 50. Dr. Jan Koch-Weser, a renowned Harvard pharmacologist, has said: "It is my belief that lack of knowledge in the proper therapeutic use of drugs is perhaps the greatest deficiency of the average American physician today." *Id.* at 282; *see also* S. GREENBERG, *supra* note 111, at 296-97.

122. Kane, *supra* note 72, at 327.

123. Adding the cost of treating ADRs (estimated at \$4.5 billion annually in hospital charges alone) to the cost of drugs, the total cost to the public of pharmaceuticals approaches 20% of all health care costs. M. SILVERMAN & P. LEE, *supra* note 22, at 17.

124. Silverman & Lee estimate that of the five to ten million serious ADRs each year, 20-30% are not foreseeable because they are caused by unpredictable patient allergy or idiosyncrasy, because foolproof prior testing is impossible, because the long delay between treatment and adverse effect prevents appropriate attribution of cause, or because the ADR leads to genetic change observable only in the next generation. *Id.* at 266; S. GREENBERG, *supra* note 111, at 284-86.

125. Full disclosure was mandated under the 1906 Act and remains the approach of other administrative agencies, notably the Securities and Exchange Commission.

126. Burger, *Government Policies and the Development of New Drugs*, in PHARMACEUTICALS IN THE YEAR 2000, *supra* note 14, at 81-106; PMA FACT BOOK, *supra* note 107, at 34-39. By contrast, Great Britain had no meaningful drug regulation until 1968. H. TEFF & C. MUNRO, *supra* note 34, at 111-18.

127. In marketing MER/29 in the early 1960s, Richardson-Merrell falsified results of animal tests, withheld negative outside reports, prepared "scientific" papers signed by "independent" investigators, and bribed physicians not to criticize the drug. M. SILVERMAN & P. LEE, *supra* note 22, at 89-94. Criminal sanctions were imposed. *See* Rheingold, *The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 CALIF. L. REV. 116, 117-21 (1968). FDA's failure to discover potential adverse reactions will continue as long as the agency depends on manufacturers for almost all of its information. *See* Merrill, *supra* note 54, at 20-23.

dollars in a drug before a single adverse reaction is reported, this misbehavior is predictable albeit unforgiveable.

A more serious problem with FDA regulation is that many ADRs are not discovered by the manufacturer. Manufacturing defects can be policed effectively,¹²⁸ but most "design defects" are not revealed by FDA methods. Current regulation emphasizes animal experimentation, which does not accurately reflect safety in humans.¹²⁹ Human populations recruited for therapeutic trials are far too small to reveal most ADRs, which occur with fairly low probability. For example, a leading authority estimates that a drug which caused a five percent increase in the incidence of fairly common birth defects (such as anencephaly or ventricular septal defect) in the offspring of women who ingested it, would likely remain unsuspected for over ten years.¹³⁰

In response to the difficulty of identifying ADRs, FDA has adopted a conservative policy for approving new drugs. The agency is additionally risk averse because of congressional and public scrutiny.¹³¹ As a result, the industry has faced increasingly high development costs that it claims outweigh the benefits of regulation.¹³² FDA's caution delays the approval of many desperately needed drugs in the United States, often for several years after their introduction in Western Europe.¹³³

A cause of action for injury based on improper marketing has been proposed. McClellan, Tate & Eaton, *supra* note 31.

128. From 1966 to 1971, 1,935 drug recalls were ordered by FDA for mistaken labelling, contamination, adulteration, or incorrect dosage. These figures, however, include nonprescription products. M. SILVERMAN & P. LEE, *supra* note 22, at 333. Apart from the sulfanilamide debacle, *see* note 28 *supra* and accompanying text, there have been few major incidents resulting from manufacturing defects. Two vaccine cases stand out: a batch of Salk vaccine with live virus caused 204 cases of polio and 11 deaths in the U.S. in 1955, and an improperly prepared BCG vaccine (used to prevent tuberculosis) killed 72 children in Germany in 1928. H. TEFF & C. MUNRO, *supra* note 34, at 108.

129. Penicillin, for example, produces harmful effects in some animals, although not in man, and might never have reached the market under current FDA regulations. H. TEFF & C. MUNRO, *supra* note 34, at 32.

130. Newdick, *supra* note 81, at 421.

131. Congress has, on occasion, severely criticized FDA when an approved drug is found to be dangerous. However, nonapproval seldom meets with Congressional objection. *See* M. SILVERMAN & P. LEE, *supra* note 22, at 251; Kennedy, *supra* note 72, at 338. The political system is highly risk averse. Inordinate attention is given to individual mistakes through the activities of Congress and the press, and errors of commission are punished more severely than errors of omission, creating barriers to innovation. Enthoven, *supra* note 17, at 655.

132. One drug industry economist, Sam Peltzman, calculated in 1974 that the cautious regulatory practices of FDA resulted in a loss to society of \$350 million each year: \$300-400 million in foregone benefits of drugs not yet approved and \$50 million from lessened competition, with a gain of only \$100 million from reduced purchases of ineffective drugs. Schnee & Caglarcan, *supra* note 110, at 102.

133. According to one study, from 1965 to 1969, new drugs appeared on the United States market one year later than in France, 1.6 years later than in Germany, and 2.1 years later than in England. Lasagna, *Research, Regulation, and Development of New Pharmaceuticals: Past, Present, and Future* (pt. 2), 263 AM. J. MED. SCI. 67, 72 (1972); *see also* PMA FACT BOOK, *supra* note 107, at 32-34; Wardell, *Introduction of New Therapeutic Drugs in the United States and Great Britain: An International Comparison*, 14 CLINICAL PHARMACOLOGY & THERAPEUTICS 773 (1973). *But see* Kennedy, *supra* note 72, at 336-38 (ascribing the delay to factors other than

C. *Improving Information in the New Medical Environment*

Drug regulation would be greatly improved if there were effective postmarketing surveillance of new drugs to trace ADRs to their source as quickly as possible and prevent additional injury.¹³⁴ There have been proposals for "Phase IV" drug regulation,¹³⁵ but these have been of insufficient breadth and duration. Widespread use of drugs requires centralized monitoring, which is currently unavailable. More importantly, drug companies have neither the incentives nor the ability to police their products in the market because of moral hazards (such as the desire to recoup costs) and inaccessibility of data. For a variety of reasons, ADRs are vastly underreported in the medical community.¹³⁶ The consolidation and increasing corporate control of medical practice offer the best chance of effective postmarketing surveillance. Liability rules and regulation designed for large HMO-dominated health care not only can promote efficient care and consumption given imperfect information, but can improve the quality and distribution of that information.

The number of reports of ADRs received by FDA has increased greatly over the past ten years, reaching almost 37,000 in 1985.¹³⁷ Guidelines adopted by FDA in 1985 emphasize postmarketing surveillance.¹³⁸ Manufacturers are now required to report within fifteen days all ADRs resulting in death, hospitalization, permanent disability, or need for drug therapy. Less serious reactions may be reported at longer intervals. Physicians and hospital pharmacists are provided with reporting forms but are not required to report directly to FDA.

regulation and advocating both "express treatment" for critically needed drugs and more FDA power to recall drugs after approval).

134. Under current policy, companies whose New Drug Applications are approved must report to FDA quarterly for the first year, semiannually the second year, and annually thereafter. PMA FACT BOOK, *supra* note 107, at 36. These requirements fall far short of creating an ideal continuous reporting system. See McClellan, Tate & Eaton, *supra* note 31, at 23-26.

135. In the late 1970s, Senators Kennedy and Javits proposed adding a Phase D to the current system which would have required testing new drugs via limited public distribution before FDA would grant full approval. Schnee, *Government Control of Therapeutic Drugs: Intent, Impact, and Issues*, in THE PHARMACEUTICAL INDUSTRY, *supra* note 42, at 19; see also H. TEFF & C. MUNRO, *supra* note 34, at 110; Kennedy, *supra* note 72, at 337; Merrill, *supra* note 54, at 17-20.

136. A 1969 study of five Philadelphia hospitals revealed that only about 5% of ADRs are reported. Reasons for not reporting ADRs include multiple drug use in hospitalized patients, confusion of reactions with the underlying disease, and doctors' and patients' reluctance to report problems. Merrill, *supra* note 44. In England during 1965 and 1966, only six deaths were reported as due to the use of aerosol asthma medications, when over 1700 deaths actually occurred according to later estimates. H. TEFF & C. MUNRO, *supra* note 34, at 109. After a substance has been found harmful, other considerations, such as fear of malpractice liability, dissuade physicians from reporting at-risk or affected patients. For example, when the DES task force recommended that doctors contact exposed patients, cooperation was less than optimal. R. MEYERS, *supra* note 4, at 210-12.

137. Faich, Knapp, Dreis & Turner, *National Adverse Drug Reaction Surveillance: 1985*, 257 J. A.M.A. 2068, 2068 (1987).

138. See Sills, Faich, Milstein & Turner, *Postmarketing Reporting of ADRs to FDA: An Overview of the 1985 Guideline*, 20 DRUG INFO. J. 150 (1986).

In 1985, about ten percent of ADR reports came directly from physicians. The proportion of physician reports citing complications of death or hospitalization was the same as for manufacturers' reports. These data suggest that both groups have roughly equal access to information and equal incentives to divulge it.¹³⁹ Consequently, legal and regulatory efforts to improve information must be directed at both groups. Information can be improved both on the supply side (that is, the accumulation of ADR reports for FDA), and on the demand side (the application of ADR knowledge to the treatment of patients).

1. *Physicians and HMOs.*

Despite the proliferation of powerful drugs which require specialized knowledge for proper use, the granting of a medical license remains a blanket privilege to prescribe. Several states and virtually all provider organizations require advanced training to perform surgical procedures, but no such training is generally required in order to prescribe drugs. Meanwhile, the inappropriate writing of prescriptions comprises half of all disciplinary actions taken by state boards of medical quality assurance.¹⁴⁰

A possible improvement would be the introduction of selective licensure procedures for the use of particularly powerful drugs or drugs which are used so occasionally in general practice that there is little opportunity to build a base of experience.¹⁴¹ In the HMO or corporate medical setting, such an approach would interfere less with care delivery than in a world of individual practitioners, since an affiliated practitioner with the requisite skill would be immediately available if needed. Selective licensure might be conditioned on formal training or on the maintenance of knowledge through continuing education dealing specifically with ADRs. Alternatively, under a uniform liability standard applicable to all providers, insurance companies might offer reduced rates to trained and knowledgeable prescribers.

Large HMOs could induce physicians to report ADRs more readily and more thoroughly. Fear of malpractice liability discourages reporting. One possible solution is a legislatively or judicially imposed duty to report possible ADRs.¹⁴² Such a duty might be most easily enforced

139. *Id.*

140. Bowen, *Congressional Testimony on Senate Bill S.1804*, 257 J. A.M.A. 816, 817 (1987). Many of these, however, represent narcotics offenses.

141. M. SILVERMAN & P. LEE, *supra* note 22, at 241, 310; Kane, *supra* note 72, at 328, 331; see notes 120-124 *supra* and accompanying text. Licensure is preferable to liability when there is a small and identifiable group of incompetent prescribers. This appears to be the case in many hospitals, where there is a core group of "superprescribers." M. SILVERMAN & P. LEE, *supra* note 22, at 295-99. A more general discussion of competence (licensure) and care (liability) is found in Shavell, *supra* note 61, at 44-45.

142. *Cf.* Tresemer v. Barke, 86 Cal. App. 3d 656, 150 Cal. Rptr. 384 (1978) (suggesting that physicians have a duty to inform patients about newly discovered risks of drugs or devices prescribed).

and most effective in large HMOs. So long as there is continuity of care at the institution, HMOs can accumulate longitudinal information about individual patients and cross-sectional information about populations much more readily than can independent practitioners. Reporting requirements backed by liability could encourage recordkeeping and the exchange of information that would make the HMO a more sophisticated drug purchaser and prescriber and hence better able to protect its patients.

2. *Drug manufacturers.*

The necessary consequence of delegating the testing of drugs to the manufacturer is that the public must rely on the company to report its findings honestly. The problem is compounded by positioning the company as an intermediary between practitioner and regulator. Although a great deal of valuable troubleshooting and education no doubt occurs through interaction between physicians and detail men, there is also potential for detail men to mislead physicians and to manipulate the reports relayed to FDA.

The dangers posed by unmonitored detail men and fraudulent marketing practices may be reduced directly by large HMOs. Such care providers are financially powerful, sophisticated bargainers who are less likely to fall prey to smooth-talking salesmen, especially if they must pay the costs associated with caring for those injured by dangerous drugs. Manufacturers are likely to change their marketing strategies if the purchasing decisions are made from above. Mass media targeted at physicians (such as medical cable television or home computer networks) may also become an increasingly economical and popular advertising tool. Such pre-prepared, uniform marketing tools can be much more effectively monitored than can detail men. In addition, greater patient involvement in health care may lead to more visible marketing techniques, such as national advertising for prescription drugs, which FDA would be able to regulate. Direct consumer advertising for prescription drugs is favored by most Americans,¹⁴³ and the need to reach these information-hungry customers may well render unprofitable the detail man's casual chats with physicians.

An important variable affecting a firm's incentive to deceive FDA and consumers is the degree of its dependence on the product in question for its revenue. While a company can take out product liability policies, it cannot buy insurance for lost profits when a drug is removed from the market.¹⁴⁴ There have been frequent proposals to reduce the patent term for drugs,¹⁴⁵ to eliminate brand names for drugs,¹⁴⁶ and to

143. *Public Advertising of Drugs Banned*, Am. Med. News, Mar. 6, 1987, at 34, col. 1.

144. Recall the case of Panalba, where Upjohn's primary goal in litigating an FDA order was to delay recall and continue to earn money. See note 113 *supra* and accompanying text.

145. M. SILVERMAN & P. LEE, *supra* note 22, at 43-45.

146. *Id.* at 185.

introduce compulsory licensure arrangements such as those that exist in Canada.¹⁴⁷ The seventeen-year patent term is largely a myth, anyway. Approximately the first five years after the patent award are spent on required testing going well beyond the "experimental use" that is excluded from the term, and new drugs are often forced into premature retirement by even newer drugs. In practice, most companies expect to recoup their investments within three years of final FDA approval.¹⁴⁸ One can argue that, rather than decreasing profit motive, shortened patent terms intensify pressure on drug companies to make quick profits and hence to suppress information about drug dangers.

In contrast to patent reduction proposals, the Drug Price Competition and Patent Term Restoration Act of 1984¹⁴⁹ extends the real patent term by allowing a manufacturer to add to the statutory seventeen-year monopoly the time lost in testing. This legislation may have the beneficial effect of reducing the original manufacturer's need to recover its investment quickly by concealing or minimizing potentially severe adverse reactions. The Act also permits makers of generic products equivalent to the patented drug to test the patented substance without infringement and to submit abbreviated applications to expedite FDA approval of the generics upon expiration of the patent, promoting the long-term development of economical generic products.¹⁵⁰

The larger the share of a firm's sales that is represented by a single drug, the more likely it is that the company will fail to deal honestly with possible adverse reactions resulting from the use of that drug. The thalidomide experience is representative. The manufacturer promoted use in pregnancy without having tested such use in animals, concealed reports of toxic effects on users and their children, and delayed withdrawal of the drug from the market. At the time, sales of thalidomide, which was distributed in Europe without prescription, constituted 46 percent of the company's turnover.¹⁵¹ Similarly, Chlormycetin accounted for 31 percent of Parke-Davis's total sales in 1963.¹⁵² A possible solution is to require drug companies to diversify their product lines, which could be achieved by compulsory licensing without necessarily eliminating smaller firms. Because the great majority of marketed products are subject to patent monopolies, there would be a minimum of associated antitrust problems.

147. See, e.g., *id.* at 313; Bony, *Compulsory Licensing Debated for U.S. Drug Makers*, Am. Med. News, May 8, 1987, at 6, col. 1. The Canadian scheme is unpopular with many manufacturers and with the Canadian public. *Id.*

148. M. SILVERMAN & P. LEE, *supra* note 22, at 35.

149. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in pertinent part at 21 U.S.C.A. § 355 (Supp. 1987) and 35 U.S.C.A. § 156 (Supp. 1987)).

150. See Daus, *Patent Term Restoration: New U.S. Legislation*, 83 PAT. & TRADEMARK REV. 81, 88-91 (1985); Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269, 300-09 (1985).

151. H. TEFF & C. MUNRO, *supra* note 34, at 3.

152. Merrill, *supra* note 54, at 27; note 118 *supra* and accompanying text.

The government has additional "sticks" at its disposal which can induce good behavior by manufacturers. Most important is that the government is the largest buyer of medical services. Moreover, in contrast to its former role as a passive third-party payer, the government currently wields far greater bargaining power through provider contracts and DRG reimbursement. For example, Medicare and other programs can establish formularies of approved drugs, thereby cutting off manufacturers who do not cooperate with FDA recommendations.¹⁵³ The federal government is even empowered to infringe patents in the public interest. A little-known exception to the patent law allows the government to authorize the manufacture of goods in violation of patents so long as the product is purchased by the government and is required for the national welfare.¹⁵⁴ The patent holder must reveal his costs and profits in court, a significant deterrent to claims, in order to recover reasonable compensation for the taking. The provision has been invoked for drugs on a few occasions, most notably in the case of the antibiotic tetracycline.¹⁵⁵

D. Summary

Imperfect information is frequently the justification for selecting liability rules. Information failure is particularly important for prescription drugs; where physicians and patients rely on manufacturers for virtually all information about drug risks; manufacturers are tempted to deny dangers to keep drugs on the market; and information about the effects of drugs in the population at large is difficult to gather. Large corporate medical structures such as HMOs and innovative legal devices to reduce manufacturers' stakes in their products can improve postmarketing surveillance and information quality in general.

IV. CONCLUSION

The law of product liability has evolved greatly over the last half century. As with many evolutionary processes, however, the outcome has been a general theme, that of consumer protection, with a large number of local variations. For prescription drugs, which are nationally marketed and regulated by FDA, the lack of a uniform federal product liability statute, the unpredictability of jury verdicts, and the expense and risk of developing new drugs threaten the availability and innovation of important treatments. This note argues that attention to

153. M. SILVERMAN & P. LEE, *supra* note 22, at 253-57. Formularies were initially supported by the 1969 Final Report of the HEW Task Force on Prescription Drugs. *Id.* at 309.

154. 28 U.S.C. § 1498 (1982).

155. M. SILVERMAN & P. LEE, *supra* note 22, at 186-88. In Britain, a similar provision, Patents Act, 1949, § 46, was used by the Minister of Health as early as 1961 to increase the bargaining power of the National Health Service as a drug purchaser. H. TEFF & C. MUNRO, *supra* note 34, at 105.

the structure of the health care industry can guide the development of the law in this area using the principles of law and economics.

Should large HMOs with near-universal enrollment control future health care delivery, a market mechanism without liability rules could lead to efficient care and consumption decisions with respect to drugs, since the HMO which purchases the drug must pay for the treatment required for any adverse effect it produces. If nonmonetary damages, such as pain and suffering, are to be compensated, a uniform negligence rule, should be applied to the entire health care industry, including drug manufacturers, since organizations will manage both the production of medical goods and the delivery of medical services. Unfortunately, many ADRs remain unpreventable because information is not optimally produced and disseminated, particularly with respect to the observation and reporting of the adverse effects of drugs already marketed. Nevertheless, HMO-dominated medical care, together with regulation that reduces manufacturers' incentives to conceal adverse effects, may improve the collection and communication of information about the risks of prescription drugs.